



Remote Accessibility to Diabetes Management and Therapy in
Operational healthcare Networks.

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1 Executive Summary

This document provides an overview of on-going technology developments and trends relevant for the REACTION project and its future exploitation, such as devices, platforms and systems. The document surveys developments in *Internet of Things* and *M2M* (Machine-to-Machine). These are two strong movements, but over time these two areas will merge, both in the commercial and the research world. The main conclusion here is that REACTION needs to consider that our monitoring technology provided to the patient will have to co-exist and function together with already existing networks of devices in the home of patients. It is not likely, or even desirable, that we can establish a separate infrastructure; REACTION will have to build on what is already available.

It is concluded that Event Management and Rule Engine technologies are highly relevant and interesting areas, where mature commercial products can easily be bought and used. For Rule Engine technology it is recommended that we evaluate Drools¹ for the third iteration.

Medical device connectivity was in focus in the first iteration of the REACTION project, and the developed REACTION Device Connectivity Kit supports many different protocols. The slow growth of the number of devices supporting the Continua standards shows that our approach to be all-inclusive and support not only Continua but ANT+ and other proprietary device protocols still remains valid, especially from an exploitation point of view.

The exploding apps market of course needs to be monitored. Numerous patient apps are already available, but we need to look for more substantial studies that verify the genuine usefulness of these apps for managing patients' diseases.

The document also recommends to closely follow the trends in *cloud computing* and the growing number of *cloud-based health services*. The overall conclusion from this technology watch is that REACTION is still well positioned with respect the on-going technology developments.

¹ <http://www.jboss.org/drools>

2 Introduction

The Technology Watch task is part of the WP2 “User Centric Requirements Engineering and Validation”. The aim of this work package is to maintain a continuous discovery and analysis of user centric requirements, needs and prospects, to be used in the design, development, implementation and validation of the REACTION platform and services. Moreover, the aim is to plan and manage user validation activities and to collect, analyse and document the results.

The work package will finally investigate all external drivers for service oriented remote health and home care environments and its deployment in European healthcare systems using a holistic approach to health status monitoring, assessment, improvement and maintenance.

The specific methodologies that will be used include evolutionary design and refinement re-engineering. Lessons Learned obtained during project progress will be used to arrive at adjustments to the initial requirements incorporating and inclusion of emergent requirements. The work package is responsible for continuously informing the work package partners of the requirement engineering process in order to enable the necessary and timely modification of design specifications and possible re-engineering of affected modules.

Predicting the future of healthcare and forecasting trends are very complicated, even more so because the healthcare system itself is very complex and it is organised differently in each country. The components that play significant roles in the formation of the trends are several, and include socioeconomic, biomedical and clinical R&D, financial incentives (e.g. payment models) and technology development. These factors influence the development and changes in the attitude of the participants of the healthcare system and the changes in the organisations. In this deliverable we will inspect the role of technological development.

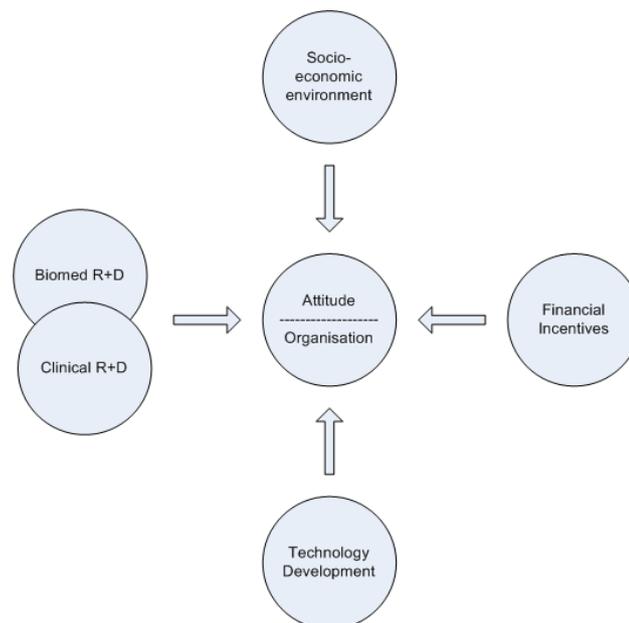


Figure 1 Components influencing the chronic care

Care for chronic diseases [Deutsch, T., Gergely, T., Levay, A. 2009] requires special considerations as it must have the following characteristics: i) continuous between visits and hospitalization periods; ii) proactive and predictive; iii) consisting of professional care provided by medical personnel and self-management provided by patients themselves; iv) influencing patient’s lifestyle; and v) dynamic, meaning that all participants should learn and adapt during the care process. Important aspects of chronic disease management are personalization, inclusion and patient empowerment. Personalization and patient empowerment are closely connected to care space evolution, i.e. the changes in physical or virtual spaces where care is provided. In this regard, Information and Communication Technologies (ICT) tools and biomedical technology act

as enabler of mobile and remote health solutions, and thus have an important role in care space evolution models.

2.1 Purpose, Context and Scope of this Deliverable

In this deliverable we will summarize the recent trends of technological development and provide an overview of the existing ICT solutions for effective management of chronic diseases such as diabetes. These solutions are considered in three groups: (i) the solutions that support various actors, (ii) solutions for various activities, (iii) solutions for various services. A special attention is devoted to the characteristics mentioned above. Moreover we will show how technology may support the extraction of new knowledge and how can it provide the information necessary for the various actors. The trends are also considered from the point of view of the REACTION project.

This report is part of the task T2.3 – Evolutionary requirements refinement.

This subtask (i.e. deliverable 2.3 - Technology watch report) will maintain a continuous observation of existing and emerging technology developments with a view to assess their impact on the requirements. It will make available periodic reports to feed into the re-engineering refinement process. The Method of work is to follow up the technological developments in the field and revise each report version with changes or updates to existing features but also on futuristic development issues.

2.2 Document Overview

The document starts with looking into important generic technology developments relevant to REACTION. The document starts with a broad perspective on technology and gradually narrows the scope down to the specific application area of REACTION, diabetes management.

The document starts by chapter 3 surveying the developments in *Internet of Things* and *M2M* (Machine-to-Machine) which are two generic technology trends which will influence REACTION. The document then narrows the scope to discuss some specific technologies relevant for the REACTION platform development including chapters 4 *Service Orchestration*, 5 *Event Management* and 6 *Rule Engines*. It then moves into discussing chapter 7 *cloud computing* and the growing number of *cloud-based health services*. Since an important aspect of REACTION is to be able to interface various medical devices we are describing the market situation for *Medical Device Connectivity* in chapter 8, where we see a rapid growth of the number of different types of devices offered for self-monitoring of vital signs and wellness activities. In chapter 9 we are looking into the growing number of *Patient Apps* for smart phones more the ones targeting diabetes patients. Chapter 10 specifically looks into *Technologies for Diabetes Management*, before chapter 11 concludes the document.

3 Internet of Things and M2M

M2M is another trend which is overlapping with IoT, and basically it can be seen as the telecom industry's vision of the Internet of Things. The focus in M2M is that everything, device or machine is connected through its own GSM/3G card.

3.1 Internet of Things

The most important overall technology trend for REACTION is the movement towards an Internet of Things, People and Services. The overall vision is an Internet where everything can be connected at any place. The idea is that not only traditional computers and phones can hook up to Internet but also sensors, devices, machines as well as real "things", like goods, and utilise this infrastructure to communicate, exchange information and invoke services in secure manner. The Internet of Things and Services is the current vision for an Internet encompassing any IT artefact, information source or service.

Internet of Things is of course not only one technology but a number of technologies being developed to fit together. In the following sections we will review the areas of IoT developments which are of most interest to REACTION.

3.1.1 RFID

The first generation applications and approaches to Internet of Things explored the use of RFID (Radio Frequency Identification) as a means of identifying and track physical objects using the Internet. Several RFID middleware frameworks are nowadays providing functionality for RFID data collection, filtering, event generation, as well as translation of tag streams into business semantics. These frameworks have been developed as part of both research initiatives [Prabhu06] and vendor products.

Furthermore, several research initiatives have produced open - source RFID frameworks, such as AspireRfid², Mobitec³, and the fosstrak⁴ project, which provide royalty-free implementations of RFID middleware stacks.

3.1.2 Service Oriented Architectures

An important cornerstone in the Internet of Things and Services is service-orientation. Wireless Sensor Networks (WSNs) have already been deployed in numerous real-time applications from various domains such as home/building automation, environmental monitoring and utility metering. WSN architectures were initially platform-dependent in order to obtain optimal performance, as well as for some marketing reasons. However, the abundance of WSN applications and the heterogeneity of sensor and actuator technologies, the need for more generic solutions that can fit to several applications at a time has risen.

Service oriented approaches aim to fulfil this gap by decoupling the functionalities of the sensors and actuators from the underlying hardware details or the network infrastructure. The Hydra⁵ project pioneered a service-oriented architecture approach based on web service technologies for connecting devices over the Internet.

Service Oriented Architectures will be discussed more in detail in chapter 4.

² <http://wiki.aspire.ow2.org>

³ <http://mobitec.ie.cuhk.edu.hk/rfid/middleware/>

⁴ <http://www.fosstrak.org>

⁵ <http://www.hydramiddleware.eu>

3.1.3 Middleware for IoT

A middleware architecture approach is of importance in the IoT domain due to its role in simplifying the development of new services and integration of legacy technologies into new ones. Middleware architectures proposed for the IoT domain often follow the Service Oriented Architecture (SOA) approach. The challenges that need to be addressed by a SOA solution in the IoT domain include: abstracting the devices' functionalities and communication capabilities, provision of a common set of services and a service composition environment.

The Hydra project pioneered a service-oriented architecture approach based on web service technologies for connecting devices over the Internet. It focused on providing developers with a high-level virtualisation layer above the physical devices and their communication interface. The proposed SOCRADES middleware architecture enables enterprise-level applications to interact with and consume data from a wide range of networked devices, including sensors. Device abstraction is achieved by device proxies that integrate low-capacity devices to the platform and expose the offered functionalities as services on the middleware. It relies on Web Services for all communication interfaces.

3.1.4 Operating Systems for IoT

For a true Internet Things to be established there is a need to have Internet-based access and control down to the lowest sensors level, i.e. that the sensors and small resource constrained devices are true Internet objects. This requires operating systems and IP-stacks to run natively and embedded in the nodes. The research into this area has been intensive. The two most prominent approaches are Contiki and TinyOS.

3.1.4.1 Contiki OS

Contiki is an open source operating system for wireless sensor networks and the Internet of things. Contiki provides low-power networking for resource constrained systems along with a development and simulation environment that makes research, development, and deployment of embedded software easy. Contiki is an event-based OS and is based on the C programming language and it is designed for microcontrollers with small amounts of memory. A typical Contiki configuration is 10 kilobytes of RAM and 48 kilobytes of ROM. Contiki contains the low-power wireless Rime communication stack, the uIP TCP/IPv4 stack, and the IPv6 Ready certified uIPv6 TCP/IPv6 stack complete with 802.15.4 6LoWPAN header compression and fragmentation.

Contiki has a complete IPv6 stack including low-power MAC layer and 6lowpan adaptation layer. Contiki's default duty-cycling MAC layer is ContikiMAC which in typical traffic load will keep the radio on less than one percent of the time. The routing mechanism in Contiki is based on IETF-RPL which is a routing protocol for low-power and lossy networks currently under standardization.

To provide a long sensor network lifetime, it is crucial to control and reduce the power consumption of each sensor node. Contiki provides a software-based power profiling mechanism that keeps track of the energy expenditure of each sensor node.

Being software-based, the mechanism allows power profiling at the network scale without any additional hardware. Contiki's power profiling mechanism is used both as a research tool for experimental evaluation of sensor network protocols, and as a way to estimate the lifetime of a network of sensors.

The Contiki OS is actively developed by a team of around 20 developers associated with many small and large companies such as Cisco, Atmel, SICS, SAP, ST Microelectronics, and Sensinode. The Contiki development community also has an active mailing list with many active Contiki users and developers.

3.1.4.2 TinyOS

TinyOS, similarly to Contiki, is an open-source (BSD license) operating system for low-power embedded wireless devices. It is also characterized by a low code and memory footprint, possibility to be used on different hardware platform and optimization of consumption and low-power communication.

TinyOS also provides its own implementation of a 6LoWPAN adaptation layer (called BLIP) plus a number of solutions to cover different communication and application issues e.g. networking, MAC, file-systems, simulators, etc. The main difference with Contiki is that TinyOS uses a slightly different approach concerning the programming language (called nesC). Any TinyOS functionality must in fact be enclosed within an entity called “module”, characterized by its “boundaries” i.e. its external interfaces.

A TinyOS interface is a set of plain C functions headers which can be configured to behave either as “commands” or “events”, according to the direction of the function call (i.e. “sent” or “received”). A TinyOS module, then, provides or uses a number of interfaces which must be connected to other modules either developed by users or provided by the OS itself, similarly to system APIs.

A TinyOS device, thus, can be programmed as a “network” of modules which exchange commands and events through pre-defined interfaces. Internally, modules are programmed in plain C language, which simplifies the TinyOS learning curve. Currently TinyOS development group is focused on branch 2.x, after a major refactoring occurred after branch 1.x to solve licensing and code organization issues. TinyOS is available to a set of different hardware platforms based on different micro-controllers families including the TI’s MSP430 family the Atmel ATmega128 family, Intel’s px27ax and others.

3.1.5 Sensor Semantics

Internet of Things requires that devices and sensors can be semantic described in order to exchange metadata about the properties and behaviour of each sensors/device. SensorML, extensions to IEEE SUMO and references to ISO 19115 [Goodwin07].

The SWAMO ontology has also been developed to enable dynamic, composable interoperability of sensor web products and services, while also providing autonomous agents for system-wide resource sharing, distributed decision making and other autonomic operations. The SENSEI⁶ project has also created an ontology towards providing a linking between observation models, procedures and complex systems.

There have also been significant standardization efforts, mainly through the SWE (Sensor Web Enablement) standards of the OGC (Open Geospatial Consortium). OGC/SWE standards do not provide facilities for abstraction, categorization, and reasoning consistent with standard technologies.

In order to overcome this gap, the W3C SSN-XG (Semantic Sensor Networks Incubator Group) has produced a generic ontology to describe sensors, their environment and the measurements they make. The ontology provides definitions for the structure of sensors and observations, leaving the details of the observed domain unspecified. This allows abstract representations of real world entities, which are not observed directly but through their observable Qualities.

3.2 M2M – Machine-to-Machine Communication

Machine-to-Machine (M2M) refers to technologies that allow both wireless and wired systems to communicate with other devices of the same ability. M2M uses a *device* (such as a sensor or meter) to capture an *event* (such as temperature, inventory level, etc.), which is relayed through a *network* (wireless, wired or hybrid) to an *application*, that translates the captured event into *meaningful information* (for example, items need to be restocked). This is accomplished through

⁶ <http://www.sensei-project.eu>

the use of *telemetry*, the language machines use when in communication with each other. Such communication was originally accomplished by having a remote network of machines relay information back to a central hub for analysis, which would then be rerouted into a system like a personal computer.

However, modern M2M communication has expanded beyond a one-to-one connection and changed into a system of networks that transmits data to personal appliances. The expansion of wireless networks across the world has made it far easier for M2M communication to take place and has lessened the amount of power and time necessary for information to be communicated between machines. These networks also allow an array of new business opportunities and connections between consumers and producers in terms of the products being.

Essentially, it is the exchange of data between a remote machine and a back-end IT infrastructure. The transfer of data can be two-way:

- Uplink to collect product and usage information
- Downlink to send instructions or software updates, or to remotely monitor equipment.

In the past, the high cost of deploying M2M technology made it the exclusive domain of large organizations that could afford to build and maintain their own dedicated data networks. Today, the widespread adoption of cellular technology has made wireless M2M technology available to manufacturers all over the world.

As shown above, wireless M2M applications include connectivity-enabled devices that use a cellular data link to communicate with the computer server. A database to store collected data and a software application that allows the data to be analysed, reported, and acted upon are also key components of a successful end-to-end solution.

While many M2M deployments will make use of short-range or proprietary radio links, mobile cellular-based M2M solutions will be preferred where mobility is required, or where high data volumes or data transfer rates are involved. Cellular-based M2M can also provide easier installation and provisioning, especially for short-term deployments.

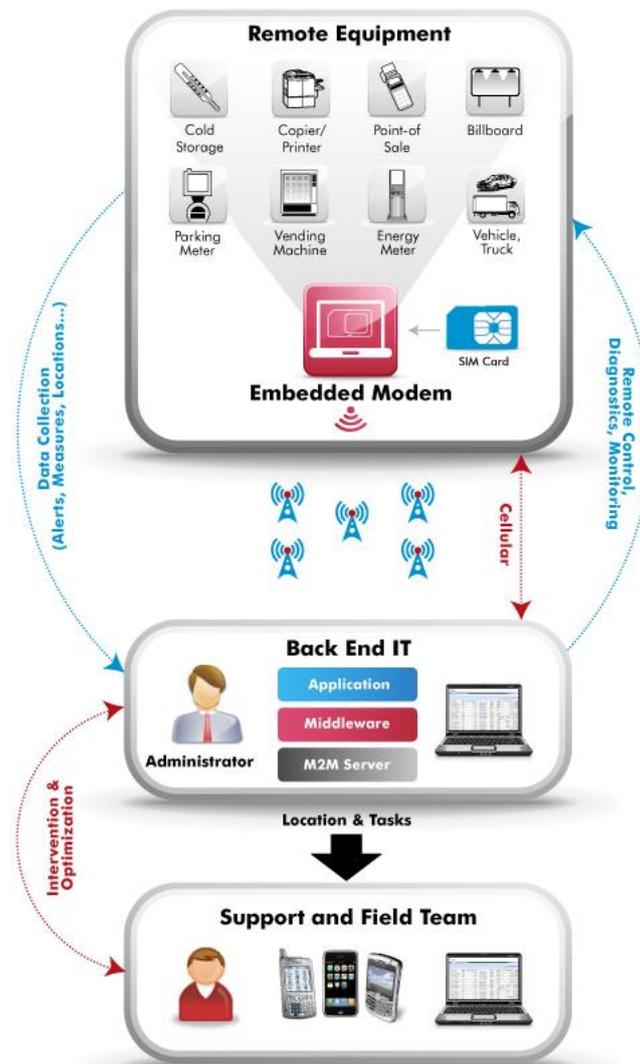


Figure 2: A typical M2M setup (from www.jasperwireless.com)

Telecoms networks will need to be optimised to cater for these new ‘subscribers’, who may have very different behaviour from current customers. Standardization is required in order to deliver cost-effective M2M solutions, and allow this market to take off.

It’s easy to see why machine-to-machine communications have so many applications. With better sensors, wireless networks and increased computing capability, deploying an M2M makes sense for many sectors.

Utility companies, for instance, use M2M communications, both in harvesting energy products, such as oil and gas, and in billing customers. In the field, remote sensors can detect important parameters at an oil drill site. The sensors can send information wirelessly to a computer with specific details about pressure, flow rates and temperatures or even fuel levels in on-site equipment. The computer can automatically adjust on-site equipment to maximize efficiency.

Traffic control is another dynamic environment that can benefit from M2M communications. In a typical system, sensors monitor variables such as traffic volume and speed. The sensors send this information to computers using specialized software that controls traffic-control devices, like lights and variable informational signs. Using the incoming data, the software manipulates the traffic control devices to maximize traffic flow. Researchers are studying ways to create M2M networks that monitor the status of infrastructure, such as bridges and highways.

The Industry in general can increase efficiencies by 10% through smart metering and operations. Traffic accidents can be reduced by 15% through intelligent traffic systems. The peak load of

electricity grids can be lowered by 20% by using smart grids. Intensive care unit time resource can be saved by 20% by the usage of smart M2M sensor systems for remote care of patients. Freight companies can double the usage level of lorries and simultaneously save fuel and reduce negative effects on the environment through smart logistics. The potential is enormous.

Examples of M2M vendors are Jasper⁷ which delivers a M2M for telecom operators and device manufacturers to implement M2M services and iMetrik⁸. ETSI is working on standardizing M2M⁹.



Figure 3 *Machine-to-machine communications can be used to monitor traffic in real time, like at this Los Angeles traffic center.*

⁷ www.jasperwireless.com

⁸ www.imetrikm2m.com

⁹ www.etsi.org

4 Service-Oriented Architectures and Service Orchestration

Wireless Sensor Networks (WSNs) have already been deployed in numerous real-time applications from various domains such as home/building automation, environmental monitoring and utility metering. WSN architectures were initially platform-dependent in order to obtain optimal performance, as well as for some marketing reasons. However, the abundance of WSN applications and the heterogeneity of sensor and actuator technologies, the need for more generic solutions that can fit to several applications at a time has risen.

Service oriented approaches aim to fulfil this gap by decoupling the functionalities of the sensors and actuators from the underlying hardware details or the network infrastructure.

Hourglass proposes a service infrastructure to publish sensor services to be used by different applications. Based on a publish-subscribe mechanism, producers (e.g., presence detection sensor) publish their services and consumers (e.g. parking place finder application) subscribe to interesting services. IrisNet suggest a sensor network at the Internet scale. It provides software components to facilitate the deployment of sensor services.

TinySOA allows programmers to access wireless sensor networks from their applications by using a simple service-oriented API via the language of their choice. Like Hydra the FP7 SANY project base its SOA implementation on Web services model. It is based on Open Geospatial Consortium (OGC) Sensor Web Enablement for the development of standards for geospatial and location-based services. SENSEI uses a RESTful model to represent any physical or virtual entities in the real world. OSaMI uses the dynamic OSGi service platform in order to address a large diversity of co-operating software-intensive systems, including sensor/actuator based systems.

IoT services can be categorised into two groups: those providing sensor data services (e.g. representing sensor resources as Web services), and high-level services (e.g. services that provide discovery, semantic reasoning, etc. The sensor data services typically gather data from various different resources and provide these as inputs to high-level services and applications (e.g. reasoning, integration, planning, and recommendation services).

An initiative towards standardising the modelling and provisioning of sensor data services is the OGC Sensor Web Enablement (SWE) [OGC'07] standards suite that is aimed at web accessible sensor networks and archived sensor data that can be discovered and accessed using standard protocols and APIs.

The standards consist of modelling schemas (Observation and Measurement (O&M) and SensorML) and Web Service interfaces (Sensor Alert Service, Sensor Planning Service and Sensor Observation Service) that facilitate the exchange of information through APIs. The research work by Henson *et al.* [Henson'09] provides a semantically enabled Sensor Observation Service, called SemSOS, which provides the ability to query high-level knowledge of the environment as well as low-level raw sensor data.

52North's SOS implementation is designed to provide a Servlet interface to sensor observation data stored in a database and the sensor descriptions stored in XML files. It proposes an ontology-based model for service oriented sensor data and networks consisting of three main components-ServiceProperty, LocationProperty, and PhysicalProperty. ServiceProperty explains the functionality of a service, while properties in the other two components describe contextual and physical characteristics of the sensor nodes in a wireless sensor network architecture.

High-level services seamlessly integrate the digital world and physical world resources to create context-aware applications and to support various data and event processing tasks. A web service enabled emergency medical response system using sensor resources in demonstrated in [Hashmi'05]. Priyantha *et al.* [Priyantha'08] describe an implementation that allows web service clients to use the sensors and at the same the proposed system minimizes code size and energy at the sensor nodes.

Some application scenarios with reasoning over the semantically annotated sensor data with rules are described in [Sheth'08] and [Henson'09]. The sensor data is annotated with concepts from the OWLtime domain ontology to allow querying for events within a time interval, using temporal concepts such as within, contains and overlaps. The rules allow dynamic assertion of events from the measured sensor values.

4.1 Service creation and orchestration environments

There are several research projects in the service creation environment area, where the focus is on an easy composition of services and not on their testability. The Unified Service Description Language (USDL) [SOA4All] is a platform-neutral service description language to support the implementation of Web-based services. USDL covers the business, operational and technical aspects of a service. USDL supports description of both atomic and orchestrated services.

Different aspects of service description are handled by defined modules within the framework, which can interact with one another. These include service level, legal, pricing, interaction, participants, functional, service and foundation.

The SOCRADES middleware supports composition of IoT-level services. It implements a service implementation repository that stores all services that are available for composition of new services, orchestration of business process or deployment. The repository stores service metadata and associated content like service implementations.

Service composition is offered through BPEL extensions that offer support for service (or hosting device) mobility. Composed services are described in BPEL, which communicates with service partners over partner links. Partner links are bound to concrete service types at design time, though the actual endpoints can be unknown. The middleware offers interfaces for deploying/un-deploying and for using the composed services.

Service creation and composition is handled by a Task Plan [Herault'10] in the SENSEI project. The framework's Semantic Query Resolver (SQR) [Herault'10] interprets a user's query for a service and translates it into a task or a combination of tasks to be executed by the framework components in order to fulfil the request. Thus, the SQR creates a task plan. A task plan may consist of a single resource operation in the simplest case. In case a single resource cannot fulfil the request, a combination of resources is determined whose interworking can lead to the desired result. In this case, the task plan consists of several atomic resources and associated operations.

The FP7 ICT m:Ciudad project⁸ introduces the concept of native mobile User-Generated Services. m:Ciudad allows users to create and provide services, and share the services and contents directly from the mobile device to other mobile users in a community. A service creation tool, the Service Creation Kit [Urdiales'09], is provided to users as a mobile application. Services can be created using templates or by using simple service elements, which can be either content or functional elements. The templates include service logic and interface implementation, but the specific parameters are not included to allow customisation.

4.2 Service and Device Discovery

Service Discovery is the process used by the system when it needs to find a service which solves a particular task or clients' needs (goals). The Service Discovery process returns a list of services that can potentially fulfil these needs. Guinard *et al.* [Guinard'10] differentiate between service discovery which is end-user driven, and network discovery of services which is machine driven and occurs at the network layer. However due to the lack of semantic information described by the service description technologies commonly used today, many service discovery mechanisms rely heavily on keyword matching and are very limited in their ability to provide the users with more complex search tools.

DPWS-based solutions [Abangar'10, Spiess'09, Guinard'10] utilize the WS-Discovery specification of the DPWS stack to find a new resource as it connects to the network and dynamically retrieve metadata about it and the services it hosts. The metadata categories include location or access rights based scopes, device type and message types.

The discovery process works as follows: when a new resource joins the network, it multicasts a 'hello' message via the UDP protocol. By listening to this message, clients/gateway middleware can detect new resources and in a second step, retrieve their metadata. To locate a specific resource or a set of matching resources for a given filter, a client can send a 'resolve' message to the same multicast group and the matching resource sends back a response directly to the client.

The Hydra project pioneered a 3-layered Discovery Architecture in IoT applications. The middleware platform provides a discovery architecture that builds on UPnP technology. The approach implements a three layered discovery architecture that includes physical device detection, UPnP network announcement and semantic resolution of devices against a device ontology.

The Hydra model driven architecture (MDA) includes a Discovery Architecture which implements the device discovery process. This architecture is structured in three layers abstracting the discovery functions. The discovery process operates both locally and remotely, so that devices that are discovered in a local network can also be discovered in a peer network over the P2P protocol implemented by the Network Manager.

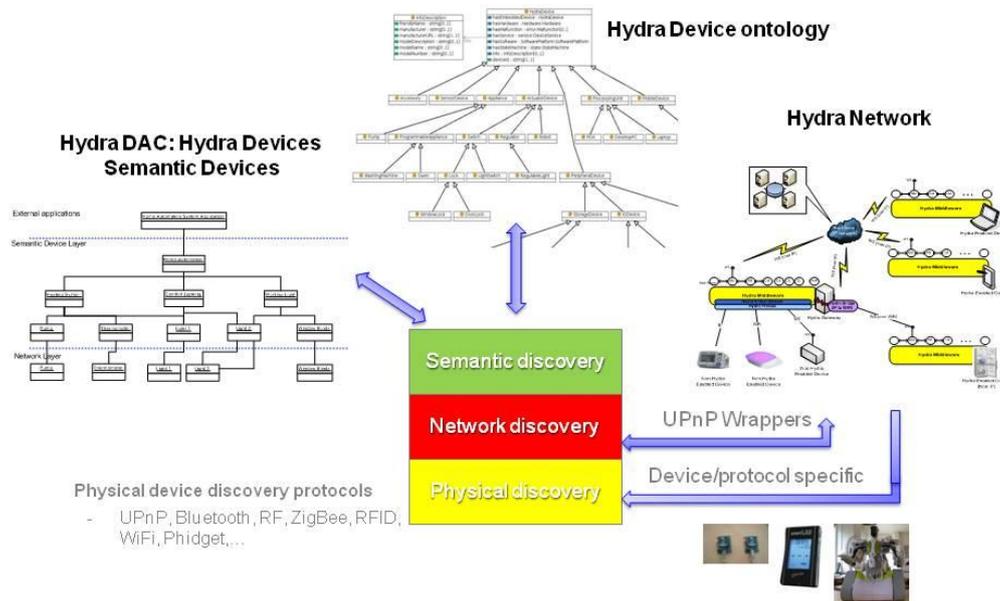


Figure 4: The 3-layered Discovery Architecture is part of the Hydra MDA.

The lowest discovery layer implements the protocol specific discovery of physical devices. This is performed by a set of specialized discovery managers listening for new devices at gateways in a local network. The second layer uses UPnP/DLNA technology to announce discovered physical devices in the local network and to peer networks.

At the top layer the device type is resolved against the Device Ontology and is mapped to some Device type. It is then placed in the *Device Application Catalogue* (DAC). If an application subscribes to events regarding this type of device, it will be notified that the device is available and has been placed in the Device Application Catalogue.

The middleware provides: 1) Discovery mechanism, 2) Low level protocols, 3) Service execution, 4) Virtualization, and 5) security and trust policies which can directly be used by the developer of Hydra applications. The middleware incorporates support for self-discovery of devices. When an IoT-enabled device is introduced the middleware is able to discover and configure the device automatically.

The SENSEI project exposes the sensor services functionalities through the Resource Directory, which accepts resource publications from resource endpoints, and can be queried by users and other components over the Resource Lookup Interface (RLI). Resource directories in different SENSEI domains can be peered. These are complemented by the Entity Directory which holds context information about resources. The SENSEI resource discovery [Villalonga'10] can be seen

from three different perspectives. The first perspective is resource oriented and focuses on the resource discovery by unique Resource IDs or other parts of the resource description. Another discovery mechanism provided by SENSEI resource directories is a simple string matching based resolution method using free text tags defined in Resource descriptions [Strohbach'10].

4.3 SoA Modelling

For more than 10 years the Object Management Group (OMG) promotes the Model-Driven Architecture (MDA) as a solution to deal with systems portability issues. In MDA, the development Method focuses on models, while code is automatically generated for various programming Languages (Java, C++, C#, Ruby) and platforms, applications servers and databases. Three layers of models are considered: Computation Independent Model (CIM), Platform Independent Model (PIM) and Platform Specific Model (PSM).

CIM captures the business level, where requirements, enterprise architecture and business processes are described with languages such as BPMN¹⁰ (Business Process Modelling Notation), Business Motivation Model (BMM) and Semantics of Business Vocabulary and Business Rules¹¹ (SBVR) issued by the OMG21.

PIM defines the architecture level describing the software architecture, applications and services.

Unified Modelling Language (UML) and SOA Modelling Language¹² (SoAML) models help in detailing the logical architecture – use cases, components, interfaces, services, orchestrations and choreographies.

¹⁰ <http://www.bpmn.org/>

¹¹ <http://www.omg.org/spec/SBVR/1.0/>

¹² <http://www.omg.org/spec/SoaML/>

5 Event Management

In REACTION there is a need to process incoming events, mainly observations, and for instance generate different types of alerts and or alarms. This work is carried out as part of work package 4. Event-driven architectures especially in combination with service-oriented approaches are a topic that has drawn much attention recently. The advantage of event driven system is that it provides a loose coupling between different subsystems which provides flexibility.

There exist several variants for designing publish/subscribe systems, which offer different degrees of expressiveness and different performance overhead. Topic-based publish/subscribe is rather static and primitive, but can be implemented very efficiently. On the other hand, content-based publish/subscribe is highly expressive, but requires sophisticated protocols that have higher runtime overhead. Additional expressiveness can be achieved by applying content-based filters in the context of statically configured topics, in particular types, to express constraints on properties that are not within discrete ranges (e.g., stock prices) [Eugster et al, 2003].

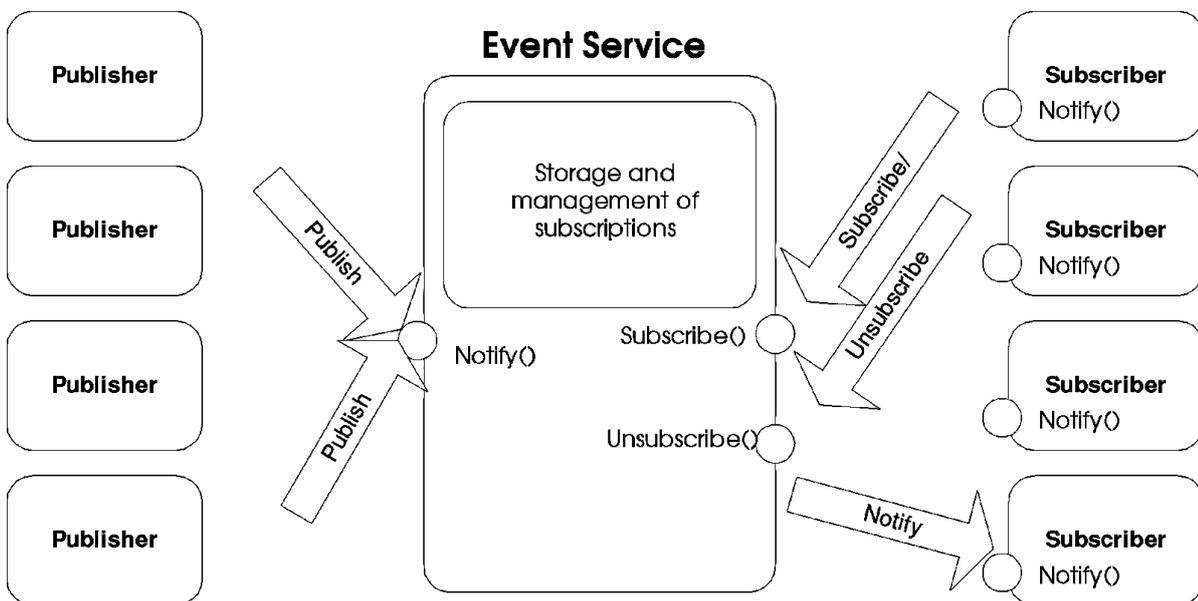


Figure 5 Publish-Subscribe A simple object-based publish/subscribe system [Eugster et al, 2003]

Large variety of emerging applications benefit from the expressiveness, filtering, distributed event correlation, and complex event processing capabilities of content-based publish/subscribe systems. These applications include RSS feed filtering, stock market monitoring engines, system and network management and monitoring, algorithmic trading with complex event processing, business process management and execution, business activity monitoring, workflow management and service discovery [Jacobsen et al, 2009].

The **DSWare** system [Shuoqi Li et al, 2004] is an event detection middleware for wireless sensor networks. In such scenarios, message delivery with pre-specified time constraints is of paramount importance. A form of hard real-time delivery is provided, but because of the severe limitations of the devices for which DSWare is designed, all the remaining features are implemented using the least resource-consuming approach. For instance, there is no support for particular message orderings.

Padres [Padres, 2011], [Jacobsen et al, 2009] is an open source distributed content-based publish/subscribe system developed by the Middleware Systems Research Group at the University of Toronto. The system Padres extends merging-based routing with imperfect merging capabilities. Content-based routing is enabled in cyclic overlays. Cyclic overlays provide redundancy in routes between sources and sinks and thus produce alternative paths between them. Padres also implements other efficient load balancing and recovery algorithms to handle load imbalances and broker failures. The Padres publish/subscribe broker is based on a content-based matching engine

that supports the subscription language, including atomic subscriptions, the various forms of historic subscriptions, composite subscriptions with conjunctive and disjunctive operators, the *isPresent* operator, variable bindings, and event correlation with different consumption policies. Padres includes a number of tools to help manage and administer a large publish/subscribe network, e.g. a monitor that allows a user to visualize and interact with brokers in real time, and a deployment tool that simplifies the provisioning of large broker networks. Padres is used in several research and development projects, e.g. in the *eQoS* project with IBM, it constitutes the enterprise service bus that enables the monitoring and enforcement of SLAs of composite applications and business processes in service oriented architectures, in collaborations with CA and Sun Microsystems, Padres is used to explore the event-based management of business processes and business activity monitoring, in collaborations with the Chinese Academy of Sciences, Padres is used for service selection and for resource and service discovery in computational Grids [Jacobsen et al 2010].

Another interesting framework was created in context the Internet of Things (IoT) research effort – **MAGIC Broker 2** (MB2) developed at the Media and Graphics Interdisciplinary Centre, University of British Columbia [Blackstock et al 2010]. MB2 middleware platform offers a simple, uniform web-based API for building IoT applications and offers developers three built-in programming abstractions: publish-subscribe event channels, persistent content and state storage, and brokerage of services via remote-procedure call. A channel is used as our namespace and conceptual container for other MB2 abstractions. It is used to name the on-line presence of things, and groups of things that comprise IoT applications. MB2 supports a state abstraction that allows clients to request the last *n* events, as well as read and write name/value pairs in a channel. MB2 can also broker synchronous two-way request-response interactions called services with devices registered with the platform (analogous to a CORBA ORB). MB2 services are similar to those supported by SOAP web services and Java RMI. MB2 supports storage and retrieval of content such as images, videos, text, and HTML documents within a channel in a consistent way. MB2 system was used to create a range of IoT applications involving spontaneous device interaction such as between mobile phones and public displays, and opportunistic or shared sensing and control of devices using a web-based sensor actuator network called Sense Tecnic (STS). The STS platform also includes facilities to process sensor data, effectively creating higher-level sensors. A complex event-processing engine [Esper] is used to process lower-level sensor events, which are sent back into MB2 for output to higher-level derived sensor feeds that can be used by applications and visuals.

Esper [Esper] is an Event Stream Processing (ESP) and event correlation engine (CEP, Complex Event Processing) – i.e. it supports requirement to process events (or messages) in real-time or near real-time. Targeted to real-time Event Driven Architectures (EDA), Esper is capable of triggering custom actions written as Plain Old Java Objects (POJO) when event conditions occur among event streams. It is designed for high-volume event correlation where millions of events coming in would make it impossible to store them all to later query them using classical database architecture. Instead of storing the data and running queries against stored data, as the databases do, the Esper engine allows applications to store queries and run the data through. Response from the Esper engine is real-time when conditions occur that match queries. The execution model is thus continuous rather than only when a query is submitted. Esper provides two principal methods or mechanisms to process events: event patterns and event stream queries. Esper offers an event pattern language to specify expression-based event pattern matching. Underlying the pattern matching engine is a state machine implementation. This method of event processing matches expected sequences of presence or absence of events or combinations of events. It includes time-based correlation of events. Esper also offers event stream queries that address the event stream analysis requirements of CEP applications. Event stream queries provide the windows, aggregation, joining and analysis functions for use with streams of events. These queries are following the Event Processing Language (EPL) syntax. EPL has been designed for similarity with the SQL query language but differs from SQL in its use of views rather than tables. Views represent the different operations needed to structure data in an event stream and to derive data from an event stream.

Generic Event Architecture (GEAR) [Casimiro et al 2007] is architecture to provide the possibility of integration of physical and computer information flows in large distributed systems interacting with the physical environment and being composed from a huge number of smart components - systems-of-embedded-systems. GEAR architecture recognises the following layers: *environment* - the physical surroundings, remote and close, solid and ethereal, of sentient objects; *body* - the physical embodiment of a sentient object; *translation layer* - the layer responsible for physical event transformation from/to their native form to event channel dialect - this layer performs observation and actuation operations on the lower side and transactions of event descriptions on the other; *event layer* - the layer responsible for event propagation in the whole system, through several Event Channels – i.e. it provides important event-processing services which are crucial for any realistic event-based system; *communication layer* - the layer responsible for wrapping events into carrier event-messages, to be transported to remote places.

GEAR utilises **Cooperating Smart devices (COSMIC)** middleware [Kaiser et al 2005] as an appropriate event model. It allows specifying events with attributes to express spatial and temporal properties. This is complemented by the notion of Event Channels, which are abstractions of the underlying network and enforce the respective quality attributes of event dissemination. Event channels reserve the needed computational and network resources for highly predictable event systems. The COSMIC middleware maps the channel properties to lower level protocols of the regular network and defines an abstract network which provides hard, soft and non-real-time message classes.

In [Hauer et al 2008] is described a flexible component framework that provides a well-defined content-based publish/subscribe service, but allows the application designer to adapt the service by making orthogonal choices about the communication components for subscription and notification delivery, the supported data attributes, and a set of service extension components. The framework uses an attribute-based naming scheme augmented with metadata containing soft requirements for the publishers and run-time control information for the service extension components. It supports different addressing schemes and interaction patterns.

TinyCOPS is the implementation of the proposed component framework aligned with the design philosophy of TinyOS 2.0. The flexibility of TinyCOPS to support different sensor node platforms, communication protocols and interaction patterns has been demonstrated experimentally. TinyCOPS makes clear distinction between the metadata and constraint and support attribute-specific operators. Conceptually, however, more important is the difference in the level of decoupling between the middleware service implementation and the communication protocols. It also allows for individual customization of the subscription and the notification delivery protocols and provides infrastructure for address information tunnelling and matching point control. TinyCOPS is concentrated on the class of relatively resource limited sensor network hardware, where compile-time optimization has comparably large impact, and where the run-time modifications are mostly limited to parameter tuning.

6 Rule Languages and Rule Engines

One important task of REACTION is to develop a rule-drive system for handling service orchestration as well as alarms and alert handling. The rules will be used to process incoming observations and take actions based on the current situation. The rules should be easy to configure and change by clinicians. In this section we survey what is available on terms of languages, tools and technologies.

6.1 Rule languages

The OWL2 RL profile is aimed at applications that require scalable reasoning without sacrificing too much expressive power. It is designed to accommodate both OWL 2 applications that can trade the full expressivity of the language for efficiency, and RDF(S) applications that need some added expressivity from OWL 2. This is achieved by defining a syntactic subset of OWL 2 which is amenable to implementation using rule-based technologies in the form of first-order logic. The design of OWL 2 RL was inspired by Description Logic Programs [DLP, 2003] and pD* [pD*, 2005].

SWRL¹³ is a W3C submission for a rule language combining the sublanguages of OWL (OWL-DL and OWL-Lite) with the Unary/Binary Datalog RuleML sublanguages. One of the goals of SWRL is to overcome the known limitations of ontology languages by adding the rules on the top of the ontologies. Anyway, the OWL-DL extension with the rules is, in general, undecidable, but decidable fragments are known (e.g. DL-safe rules).

The main strengths of SWRL are its simplicity and its tight integration with OWL. SWRL extends the OWL axioms with Horn-like rules combined with the knowledge-base. Rules are of the form of an implication between an antecedent (body) and consequent (head). The intended meaning can be read as: whenever the conditions specified in the antecedent hold, then the conditions specified in the consequent must also hold. Usually, SWRL rules are part of an OWL ontology encoded in XML or in abstract syntax, which is quite hardly human readable. SWRL is increasingly supported by DL reasoners, e.g. KAON2 [KAON2], Pellet [Pellet], Racer-Pro [Racer], Hoolet [Hoolet] or Boosam [Boosam].

WSML-Rule is the rule based sublanguage of Web Service Modelling Language (WSML) [WSML, 2008] specified as the formalization of Web Service Modelling Ontology (WSMO) [WSMO]. The rules are defined as the logical expressions in WSML. Basically, the logical expression syntax has its foundations in F-Logic [Kifer, 1995], but uses slightly different language keywords.

WRL (Web Rule Language) is a rule-based ontology language for the Semantic Web [WRL, 2005]. The language is located in the Semantic Web stack next to the Description Logic based ontology language OWL. WRL defines three variants, namely Core, Flight and Full. The Core variant marks the common fragment between WRL and OWL. WRL-Flight is a Datalog-based rule language. WRL-Full is a full-fledged rule language with function symbols and negation under the Well-Founded Semantics. WRL has an XML exchange syntax which is based on RuleML.

SWSL-Rules are a logic-based language for specifying formal characterizations of Web service concepts and descriptions of individual services. It includes two sublanguages: SWSL-FOL - a full first-order logic language, which is used to specify the Semantic Web Service Ontology (SWSO), and SWSL-Rules - a rule-based sublanguage, which can be used both as a specification and an implementation language [SWSL, 2005].

SWSL has not been implemented extensively yet. This is because the SWSL effort has to date focused mainly on requirements, specification, and use case scenario development. SWSL plans to embark upon more ambitious implementation efforts, largely using tools for RuleML and F-Logic,

ERDF is an extension of RDF adding the support of negation and the rules [Wagner, 2008]. RDF does not support any negation concept, thus ERDF comes with the two types of negation:

¹³ <http://www.w3.org/Submission/SWRL/>

- Negation as failure - also called weak negation, it is intended to decide if it is possible to prove a specific ground fact.
- Strong negation - is used to explicitly provide negative information in the knowledge base.

For more, ERDF adds the rule support to RDF. The rules can be defined in two ways: (1) an XML syntax expressed with the help of R2ML and (2) a non-XML syntax, based on Jena Rules syntax, which is extended with support to express the negation. The ERDF implementation is realized as the extension of Jena API [Jena2].

6.2 Rule mark-up languages

RuleML is a mark-up language developed to express both forward (bottom-up) and backward (top-down) rules in XML for deduction, rewriting, and further inferential-transformational tasks [RuleML]. It is defined by the Rule Markup Initiative, an open network to develop a canonical Web language for rules using XML mark-up and transformations from and to other rule standards/systems.

RuleML has defined several sublanguages, such as:

- Object-Oriented RuleML: the frame-like knowledge representation supporting the facts (instances) and rules (methods).
- ASP RuleML: support for answer-set programs in XML Schema. This variant facilitates the specification of a number of ASP-related constructs in a general manner. Moreover, it constitutes a base language for specific ASP extensions, such as HEX-programs.
- RDF: An experimental RDF translator for a subset of RuleML, available in XSLT
- RuleML Lite: developed basically as a RuleML subset compatible with RDF and OWL-DL that covers unary and binary Datalog facts, rules, and queries. The RuleML Lite design has interacted with the SWRL design via the joint committee.
- FOL (First Order Logic) RuleML: shares/reuses most of the earlier RuleML LP syntax, incorporating First-Order-Logic quantifiers and disjunctions as well as equivalence and negation. FOL RuleML strives for a strict separation of declarative content from procedural performatives.

R2ML is a comprehensive and user-friendly XML rule format that allows interchanging rules between different systems and tools, enriching ontologies by rules, connecting the rule systems with R2ML-based tools for visualization, verbalization, verification and validation [R2ML].

R2ML is comprehensive in the sense that it integrates:

- the Object Constraint Language (OCL): an OMG standard used in information systems engineering and software engineering [OCL],
- the Semantic Web Rule Language (SWRL): a proposal to extend the Semantic Web ontology language OWL by adding implication axioms,
- the Rule Markup Language (RuleML)

R2ML is a *usable* language in the sense that it allows structure-preserving mark-up and does not force users to translate their rule expressions into a different language paradigm such as having to transform a derivation rule into a FOL axiom, an ECA rule into a production rule, a function into a predicate, or a typed atom into an untyped atom.

Notice that R2ML, like OCL and OWL/SWRL, provides a *rich syntax* for expressing rules supporting conceptual distinctions, e.g. between different types of terms and different types of atoms, which are not present in standard predicate logic. However, the user does not have to be familiar with all of R2ML's language elements in order to use it productively.

6.3 Rule Engines

A rule engine is the software platform that interprets rules, expressed in a rule language, and executes them.

6.3.1 Drools

One example is Drools which is split into 5 modules - Guvnor (BRMS/BPMS), Expert (Rules), Fusion (CEP), Flow (Process/Workflow) and Planner. Guvnor is a web based governance system, traditionally referred to in the rules world as a BRMS. Expert is the traditional rules engine. Fusion is responsible for the event processing side. Flow is the workflow module.

The background of this systems lies in the research field Artificial Intelligence and more specifically in the field Knowledge Representation. In this field, one is concerned with formally representing knowledge in a knowledge base and to do reasoning with this knowledge base. This means, that we want to infer conclusions from the facts stored in the knowledge base and in this way, make implicit knowledge explicit. Drools is a Rule Engine that uses the rule-based approach to implement this reasoning procedure (Proctor, et al., Drools Expert User Guide, 2011).

Drools rule system is Turing complete, with a focus on knowledge representation to express propositional and first order logic in a concise, non-ambiguous and declarative manner (Proctor, et al., Drools Expert User Guide, 2011). Its main component is an inference engine that is able to scale to a large number of rules and facts. This engine matches facts and data against rules to infer conclusions which result in actions. This matching of new or existing facts against rules is called pattern matching. A rule has two-parts. In both parts first order logic is used as representation language. The structure of a rule is as follows:

```
when <conditions>
then <actions>;
```

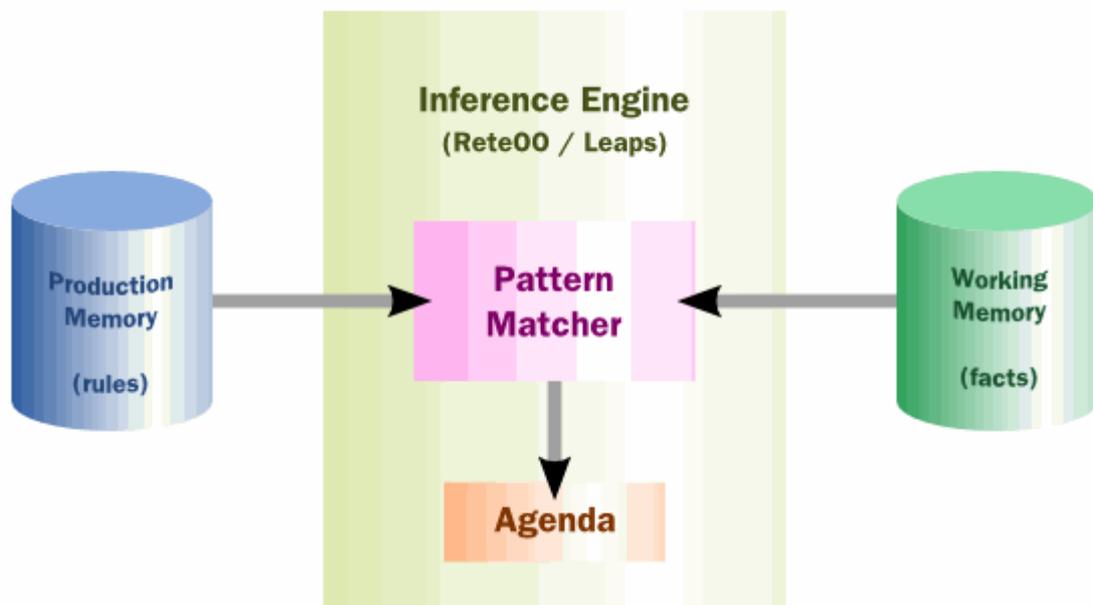


Figure 6: High-level view of a Rule Engine (Proctor, et al., Drools Expert User Guide, 2011)

The rules in Drools are stored in the so-called production memory as it is depicted in Figure 6. Facts instead are asserted into the so-called working memory where they may then be modified or retracted. The inference engine takes the facts from the working memory and does pattern matching against the rules in the production memory. In this process, it can happen, especially for a system with a large number of rules and facts, that many rules being true for the same fact assertion; these rules are then said to be in conflict. Another component of the inference engine,

the Agenda manages the execution order of these conflicting rules using a conflict resolution strategy (Proctor, et al., Drools Expert User Guide, 2011).

There are two working modes for the inference engine in Drools. One is goal-oriented and it is called backward chaining, which is also the method the programming language Prolog is using. For this method of execution, a goal is tried to be proven. If this is not possible, the goal is broken down into sub goals which now in turn are tried to be satisfied. So far, Drools has only limited, experimental support for backward chaining (Proctor, et al., Drools Introduction and General User Guide, 2011). The other method of execution is “data-driven” and it is called forward chaining. For this method, which is reactionary, facts are being asserted into the working memory. This normally leads to one or more rules being concurrently true and firing. Which of the rules are then scheduled for execution is determined by the agenda component. The whole process is also shown in Figure 7 and be summarized as: its starts with a fact, which is then propagated and ends in a conclusion. At the moment, Drools is mainly a forward chaining engine (Proctor, et al., Drools Expert User Guide, 2011).

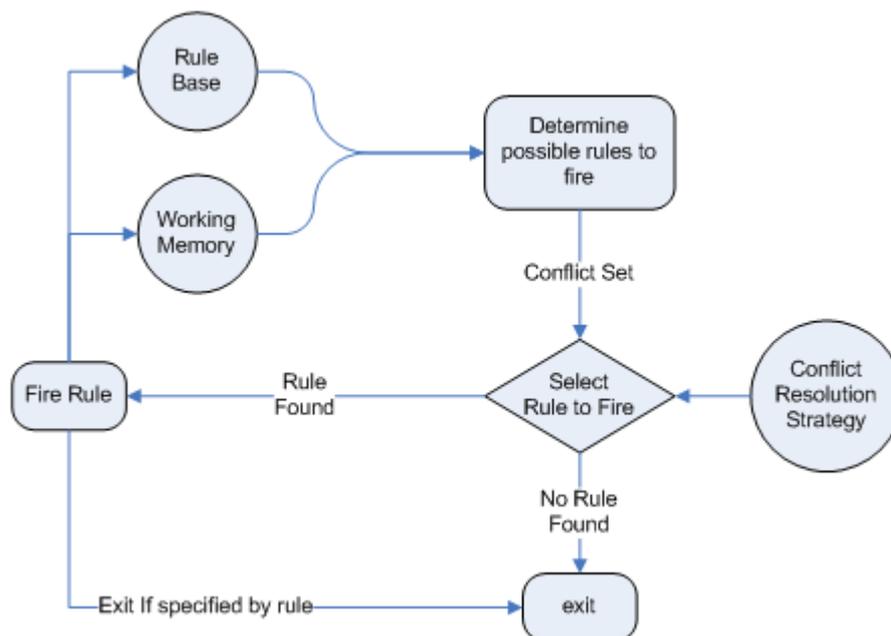


Figure 7: Forward Chaining (Proctor, et al., Drools Expert User Guide, 2011)

As there are other forms of knowledge representation and reasoning techniques, the question arises, why we should use a rule engine like Drools in REACTION. A rule engine has many advantages, the following mentions the most important ones (Proctor, et al., Drools Expert User Guide, 2011):

- **Declarative Programming:** Rules specify in a natural and understandable way, what should be computed. The question of how something is then computed is hidden inside the system.
- **Logic and Data Separation:** The data is in the domain objects, the logic is in the rules. This probably leads to a much easier maintenance and update of the logic as the general world knowledge is separated from specific data instances. This proposition can be especially true if the logic is cross-domain or it is a multi-domain logic.
- **Speed and Scalability:** The used algorithm provides very efficient ways of matching rule patterns to the domain object data. This holds especially, when the datasets only change in small portions as the rule engine can remember past matches.
- **Explanation Facility / Understandable Rules:** Drools Expert effectively provides an "explanation facility" by being able to log the decisions made by the rule engine along with why the decisions were made. Additionally, Drools allows for rules that are very close to natural language.

Drools provides a business rule manager with user friendly interfaces which provides for multiple users of different skill levels to access and edit rules and processes (Proctor, et al., Guvnor Manual, 2011).

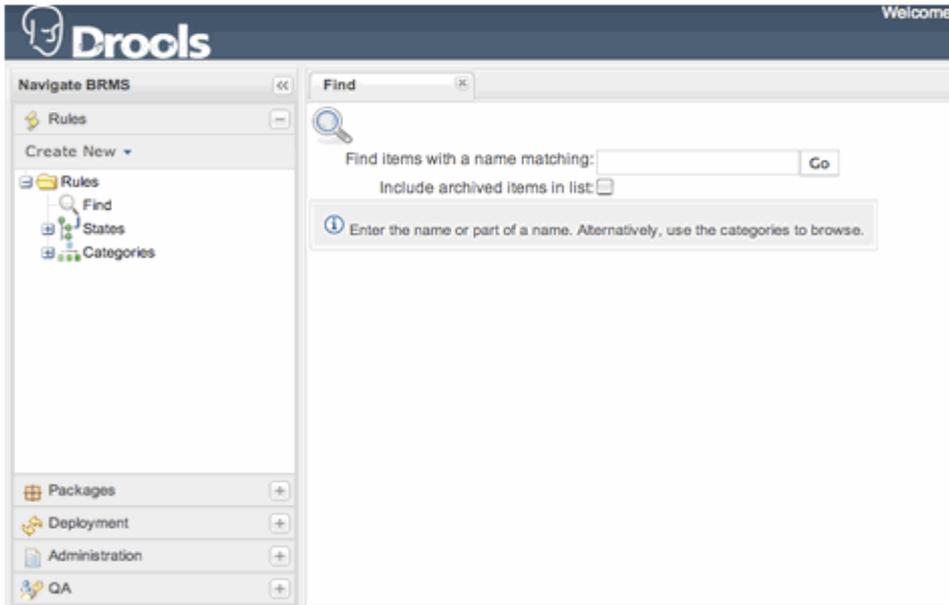


Figure 8: Drools Guvnor – a Business Rules Manager (Proctor, et al., Guvnor Manual, 2011)

Guvnor provides a WebDAV API such that the repositories can be accessed over http. For domain experts, which are not used to think in rules, the Drools Guvnor guided editor provides a wizard like way to create and edit rules through a graphical interface, which is shown in Figure 9.

Guided rule editor

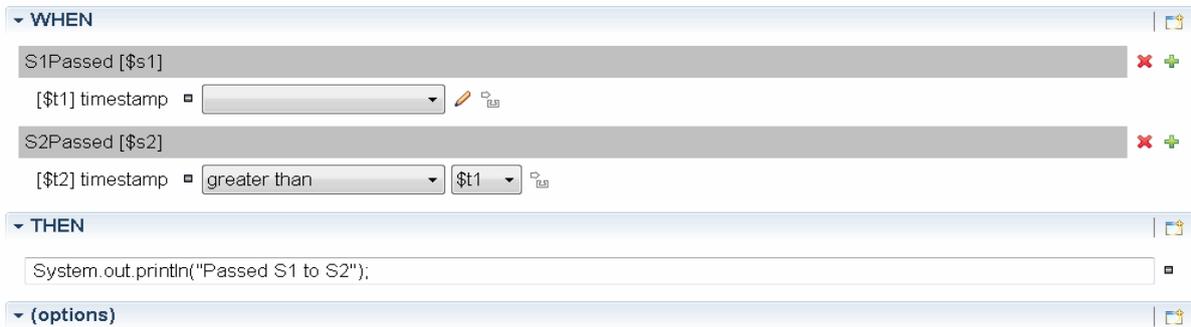


Figure 9: Graphical Rule Editor

7 Cloud Computing and Cloud-based Health Services

One of the strongest trends in the IT industry is that a growing number of companies base their IT strategy on cloud-based resources, spending little or no capital to manage their own IT infrastructure. Cloud computing is an important development for the REACTION project to consider, both from an exploitation perspective, and the possibility to deliver REACTION as a cloud service should be available, and from a deployment perspective such cloud service could be used to implement the whole or parts of the platform.

7.1 Cloud Computing

Cloud computing was first popularised in 2006 by Amazon's Elastic Compute Cloud, which started offering VMs (virtual machine) for 10 cents/hour using both a simple web interface and a programmer-friendly API. Amazon EC2 thus became an early driver of a utility computing model with the IaaS (*Infrastructure as a Service*) paradigm becoming closely associated with the notion of cloud computing. An IaaS cloud enables on-demand provisioning of computational resources, in the form of VMs deployed in a cloud provider's data centre (such as Amazon's), minimising or even eliminating associated capital costs for cloud consumers, allowing capacity to be added or removed from their IT infrastructure in order to meet peak or fluctuating service demands, while only paying for the actual capacity used.

Over time, more IaaS cloud providers, such as GoGrid, RackSpace, FlexiScale, ElasticHosts or CloudSigma have emerged. Other providers offer products that facilitate working with IaaS clouds, such as rPath's rBuilder, which enables dynamic creation of software environments to run on a cloud.

In general, an IaaS cloud consists of two main components, namely: a virtualisation layer on top of the physical resources including network, storage and compute; and the cloud management system that controls and monitors the VMs over the distributed set of physical resources and exposes a cloud interface that provides the users with a simple abstraction to manage VMs. In recent years, a constellation of technologies that provide one or more of these components has emerged. So, a variety of hypervisors have been developed and greatly improved, most notably KVM and Xen in the open source field, and VMware and Hyper-V in the proprietary software field. Also several cloud management technologies that cover the functionality outlined above have appeared in the proprietary commercial field, like Platform ISF16, or VMware vCloud Director, or in the open-source field following an open core model where the interesting and relevant features are proprietary, like Eucalyptus or AbiCloud.

More recently concepts like PaaS (*Platform as a Service*) and SaaS (*Software as a Service*) have emerged as complementary cloud technologies to IaaS. PaaS means that the provider offers a hardware and software platform on which users can develop and deploy new applications and service. IaaS is the best choice when putting existing legacy systems on to the cloud, while PaaS is seen as the best choice when developing new systems and services. SaaS means the cloud provider offers an application as a service, for instance a project management and collaboration tool like ProjectPlace¹⁴.

Currently a number of open standards address interoperability and portability issues surrounding cloud infrastructures¹⁵. For the infrastructure level, open standards like OCCI, CIMI, CDMI and OVF are increasingly gaining a lot of attention from cloud providers and consumers:

- *Open Cloud Computing Interface*¹⁶ (OCCI), which is developed by the Open Grid Forum, defines a set of specifications dealing with the management of arbitrary cloud resources. Although initially only the IaaS use case was targeted, the specification has been extended

¹⁴ <http://www.projectplace.com>

¹⁵ <http://cloud-standards.org/>

¹⁶ <http://occi-wg.org/>

for the recommended version 1.1 to also accommodate PaaS and SaaS scenarios by providing a strong focus on extensibility and adaptability.

- *Cloud Infrastructure Management Interface (CIMI)*, developed by the Distributed Management Task Force (DMTF) specifies a RESTful interface for the management of the IaaS layer by modelling it as a logical service domain. An accompanying specification defines the Common Information Model (CIM) representation of this logical model.
- *Cloud Data Management Interface (CDMI)*, developed by the Storage and Networking Industry Association (SNIA) is a complementary standard for data management defining a RESTful interface which allows the management of data objects and the associated metadata. It supports the concept of providing export protocols such as NFS, CIFS, or FC to access data according to specific use cases. The specification of OCCI and CDMI are connected to clearly define mutual use.
- *Open Virtualization Format (OVF)*, developed by DMTF is an open standard for packaging virtual appliances. It defines an “open, secure, portable, efficient and extensible format for the packaging and distribution of (collections of) virtual machines”.

7.2 Cloud-based Health Services

One beneficiary implementation would be to open up the REACTION platform for external applications and services such as Microsoft HealthVault. This could reinforce the scope of the project and unfold its acknowledgement as well. Here, we next review what services these external applications give and briefly discuss their effective output within the REACTION project. By doing so the REACTION project will also comply with possibly the most important European strategic objectives in eHealth: to provide interoperability among healthcare information systems. The CEN/ISSS eHealth Standardisation Focus Group has identified five prominent strategic aims of healthcare informatics in Europe to be (CEN/ISSS 2004) and could work as a finger-post in the upcoming project iterations:

- Improve access to clinical records.
- Enable patient mobility and cross border access to healthcare.
- Reduce clinical errors and improving safety.
- Improve access to quality information on health for patients and professionals.
- Improve efficiency of healthcare processes.

7.2.1 HealthVault

One way online health services are put to real is by Microsoft HealthVault¹⁷ and the growing ecosystem of connected, patient-friendly applications. By HealthVault people can store copies of their health records obtained from several sources, upload information from health and fitness devices, provide their information to healthcare providers and access other products and services. In HealthVault, one easily accessible personal account, people can consolidate their health information and help them become more informed and active in managing their health.

¹⁷ <http://www.healthvault.com>



Figure 10: Microsoft HealthVault platform and various Online services.

HealthVault can be said to offer a central repository for health information that people gather from across a wide spectrum of healthcare. The HealthVault platform also supports the growing ecosystem of connected, user-friendly applications (e.g. REACTION to be), so people can keep a simple and comprehensive, up-to-date record of their health information in a way that is configurable by which they can view and share it with whomever they choose.

The HealthVault Platform gives a web-based API layer that provides data and infrastructure services upon which all HealthVault applications are built. It includes a web application that provides an explorer type UI for the HealthVault Platform as well as being the key middleman web based authentication. The API specification is bounded to the system description level and makes no claims related to the user interface or APIs that a system might implement. HealthVault Service communications occur via a schematized XML in the body of an HTTP request over a TLS Connection. The HTTP requests further must be submitted using the POST HTTP verb. The schemas for the XML body conform to W3C's XML Schema 1.0 Standard.

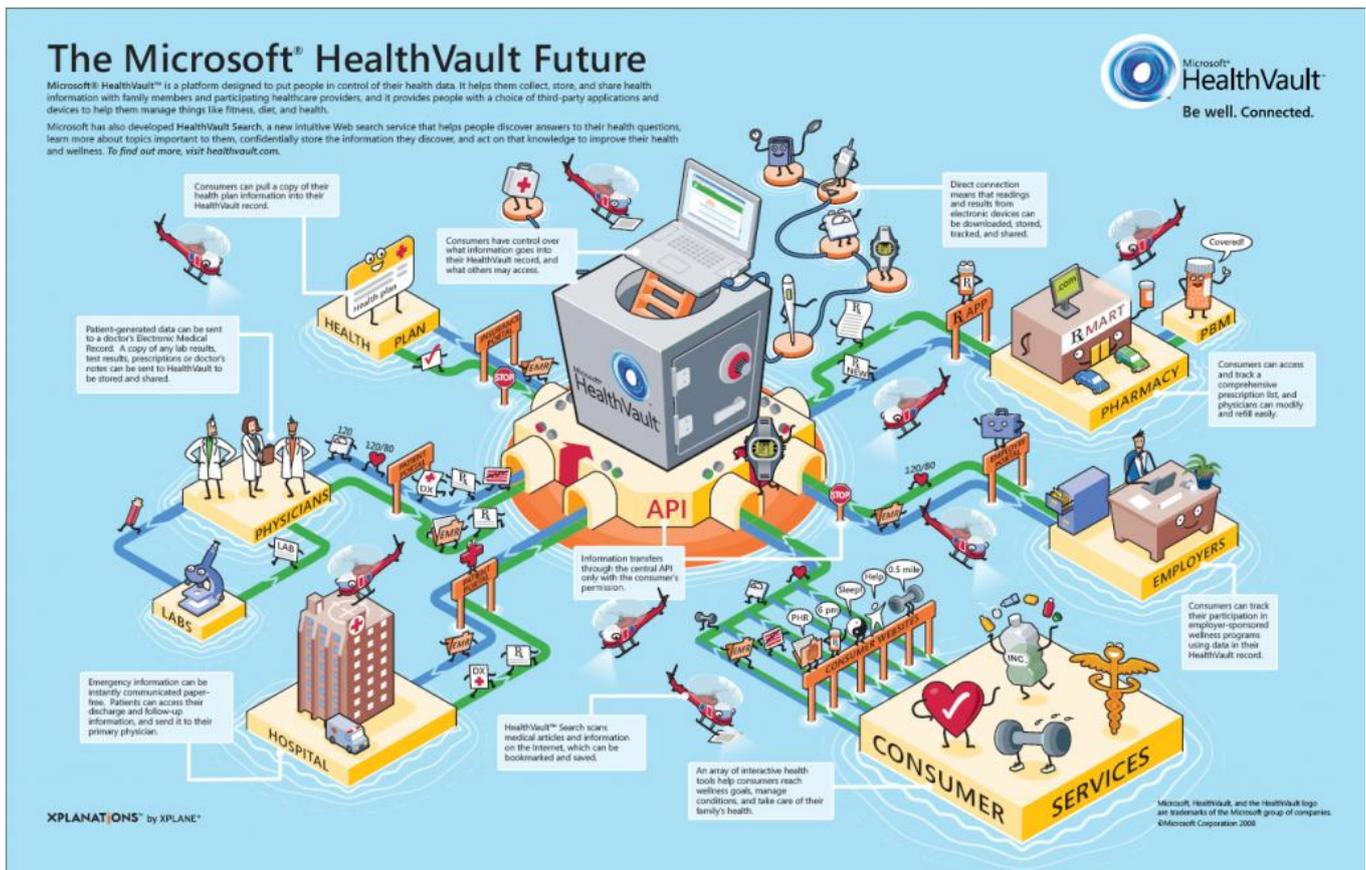


Figure 11: shows the Microsoft HealthVault platform architecture

7.2.2 MEDgle Cloud

Another cloud based service is the MEDgle Cloud¹⁸. It provides robust webscale solutions for clinical assessment and evaluation support. The service is accessible via the web and mobile. In practical terms it is a semantic web (Web3.0) service that transforms probabilistic medical concept relationships (i.e. symptoms, diagnoses, tests, medication, etc.) into artificially intelligence based algorithm actions. Consumers of the service may then use it to query a comprehensive relationship database and use the Clinical GPS tool (using over 100 million data-points and complex algorithms) as a powerful analysis engine with a wide range of real-time and predictive health uses. A sample of a symptom query type XML can be found here: <http://www.medgle.com/xml.jsp?task=getinfo&q=fever>

7.2.3 2net Platform

The 2net Platform is a cloud-based system designed to be universally-interoperable with different medical devices and applications. It enables end-to-end wireless connectivity while allowing medical device users and their physicians or caregivers to easily access biometric data. As it comes with two-way connection capabilities and a broad spectrum of connection options, it adds flexibility on how medical data is managed.

There are four gateways onto the 2net Platform's data centre:

- A standalone FDA-listed external device -- the 2net Hub*
- Medical devices with an embedded cellular component

¹⁸ <http://www.medgle.com/>

- Medical data sent from mobile phones
- Service platform integration between the medical grade 2net Platform to customer and collaborator service platforms using application programming interfaces (APIs)

The 2net Platform¹⁹ supports SSL secure communication of data and is FDA listed as a Class I Medical Device Data System (MDDS) where it is designed, developed and manufactured in accordance with a quality system compliant with ISO13485 standards. This means that it aligns with the quality requirements of U.S. and international regulatory agencies in the healthcare industry.

¹⁹ <http://www.qualcomm.life.com/wireless-health>

8 Medical Device Connectivity

InMedica, a medical electronics market research group within IMS research (a leading independent provider of market research and consultancy to the global electronics industry), came up with a quantitative market assessment²⁰ for the world Telehealth market in 2011. In that assessment report it is estimated that Remote Patient Monitoring (RPM) is already highly relevant in the treatment of chronic diseases but that it also will increase over the next coming years. Medical devices that are deployable within the patient homes and make part of Telehealth services (e.g. Blood Glucose Meters, Pulse Oximeters, Weighing scales, Blood Pressure Monitors) are regarded to play a key role in the management of diabetes and hypertension which are two out of four main chronic disease managements (Figure 12).

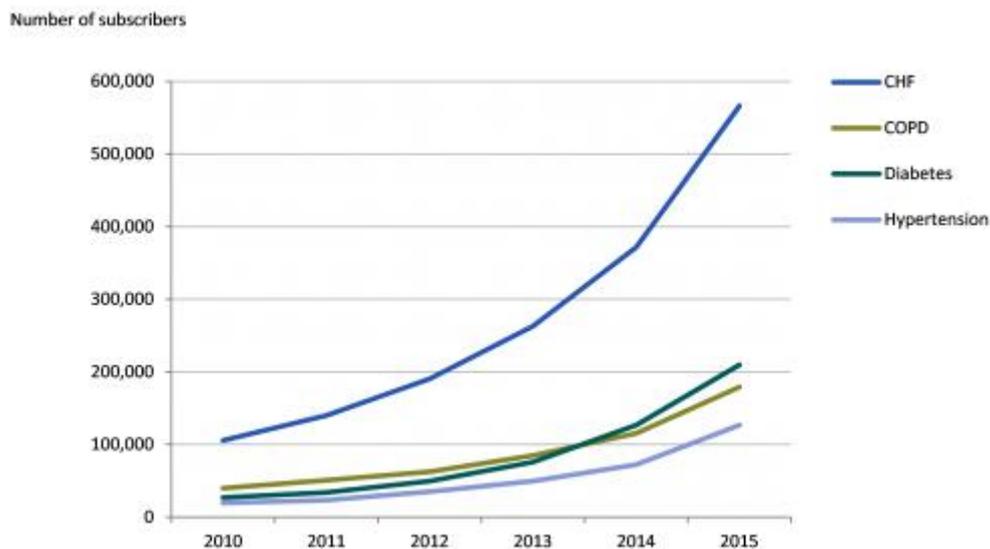


Figure 12 World Telehealth market graph with subscribers per disease.

This all sounds like a good foundation to build any business models for the REACTION consortium but what happens when a software platform becomes target for deployment restrictions? In Sweden, there is a rise in the number of software-related injuries and even deaths. Through the Swedish Medical products agency, the country asked the European Commission (EC) if it could be possible to handle unregulated software within EU. The initiative is expected to reach its culmination in early 2012. This is also when the EC is to publish guideline manuals assisting software manufacturers and regulators in determining if independent medical software should carry the CE mark or not (Cobbaert, 2011).

What is then available as guidance in avoiding any possible future restrictions on qualified medical devices and software is that the classification itself depends on whether or not the device or software falls within the scope of the Medical Devices Directive (i.e. MDD; 2007/47/EC).

Currently, the directive states that software can indeed be qualified as a medical device but unfortunately the directive does not specify what exact kind of software will meet the medical device definition per se. This uncertainty has led to various interpretations among EU member states and private vendors and developers, creating an uneven playing field for companies. The upcoming EC guideline will provide clarity in this issue.

If REACTION should act as a “closed-loop-system”, i.e. give decision support to patients and/or caregivers it has to be treated as medical device with all its consequences. At end the “intended use” of the REACTION system is the base for this classification. For the in-hospital application it is quite clear as it gives insulin dosing support for clinicians and as a medical

²⁰ http://in-medica.com/press-release/Global_Telehealth_Market_Set_to_Exceed_1_Billion_by_2016

device its development is according to the MDD. Later, when and if, the in-hospital application would be a part of the rest of the REACTION system, then also the whole system would be a medical device.

8.1 New Device Technologies

When a medical device becomes a new technology within RPM it can be said that it satisfies a higher order of use. This means that it does not only create a scope of use for the patient but will at the same time ease and improve the understanding for the clinician on what actually is happening with his or her patient when at home. In the transaction of this medical devices usually declare its objectives within such environment and that is what we will see here in chapter 8.1.

8.1.1 Communication protocols

In order to make any kind of a device communicate with a gateway or a platform client of some kind it is important that it can seamlessly be integrated. The REACTION project is adopting the Continua Health Alliance guidelines²¹ that describe a set of standards that are developed in order to allow vendors, solution developers and sharers of various types of health related information to easily share the data. Some of the communication protocols supported are described here:

8.1.1.1 Bluetooth

Bluetooth is an open wireless technology standard for exchanging data over short distances from fixed and mobile devices, by using short length radio waves and creating personal area networks (PANs). Bluetooth was initially created by telecoms vendor Ericsson in 1994, and today is managed by the Bluetooth Special Interest Group. It can, in its current specification, connect several devices, forming small short range networks.

8.1.1.2 ZigBee

ZigBee is a WPAN standard for a suite of high level communication protocols using small, low-power digital devices with short range radios. ZigBee is typically used for industrial automation and domestic light control applications.

8.1.1.3 USB

The Universal Serial Bus (USB) is a wired point to point connection technology that is capable of high throughput (480Mbit/s for USB 2.0 and 4800Mbit/s for USB 3.0). The USB signals are transmitted through a twisted-pair data (channels) cable and prior to USB 3.0 these commonly used half-duplex differential signalling to reduce the electromagnetic noise effects in long lines. The USB 3.0 uses far more complex by introducing two additional pairs of shielded twisted wires and interoperable contacts. These data channels permit a higher data rate as well as full duplex operation. A USB connection is always between a host (or a hub, e.g. PDA) at the connector end and a device (or hub's upstream port, e.g. a biosensor's transport gate) at the other end.

8.1.1.4 Wi-Fi

A wireless fidelity (Wi-Fi) network is used to connect computers to each other, to the Internet, and also to wired networks. Current Wi-Fi networks operate in the ISM bands (2.4GHz,

²¹

http://www.continuaalliance.org/static/cms_workspace/Continua_Free_Guidelines_Release_1.11.12_Continua_Health_Alliance.pdf.

5GHz), offer speeds up to 54Mbps and support quality of service (QoS) with managed levels for data, voice as well as video applications.

8.1.1.5 Li-Fi

Li-Fi (Light Fidelity) is the optical version of Wi-Fi and the newly launched Li-Fi Consortium²² says that the technology will provide a secure, reliable and ultra high-speed wireless communication interfaces that relies on GigaSpeed technology, an optical mobile technology with several Li-Fi environmental features and service. It will use already existing communication technology or technical topics regarding optical wireless communication in order to increase available services in the consumer area, industry, medical area or in logistics. Li-Fi for medical devices in the future is a force to count on.

8.1.1.6 IPv6

The Internet Protocol version 4 (IPv4) is today suffering from an acute shortage of available address space for allocation (with what is the standard of 32 bits). The reason behind it is the exponentially increasing network devices that are connected both in the wired and the wireless domain. Therefore, there exists a 6th version, IPv6 (with what is to be the new standard address space of 128 bits) to the currently exhausted IPv4. Although communication technologies such as the IEEE 802.15.4 (IPv4 (and v6)) has been developed in a rapid pace the applications that make use of smart objects have not and this due to proprietary or half-closed systems with partial or non-interoperable systems, i.e. computers communicating with their own protocols via complex multi-protocol gateways. This has been a technological discomfort so far but as these networks today more and more operate on fully E2E IP-based architectures one could assume the problem would be dissolved. But when it comes to sensor architectures that do not rely on an IP-basis and instead deploy a protocol-translation gateway model they thereby re-energize the problem of complexity (non-efficient network fragmentation due to inconsistent routing, QoS, transport and network recovery techniques) of multi-protocol gateways. IPv6 is a good alternative to design a scalable and efficient network that uses a vast number of communicating smart objects.

8.1.2 Tools and Resources

There are some tools and resources available online although these are more or less similar and build on the same technical approach. They could possibly assist in realising the communication strived by the Continua Guidelines.

8.1.2.1 Wipro Continua Toolkit

This toolkit enables medical device to get compliant to the Continua specified protocol, i.e. IEEE 11073-XXXXX, and it contains a Wipro Continua Agent and a Wipro Continua Manager. The Agent is a library component with a well-defined APIs and portable ANSI C source code for multiple sensor and device specializations. The Manager is on the other hand capable of supporting multiple Continua Agent enabled medical devices in order to retrieve data via USB, Serial, Bluetooth and TCP/IP. The toolkit works on various types of platform both handheld devices and desktops. It works with OEM devices such as pulse Oximeters, glucose meters, weight scales and blood pressure monitors.

²² <http://www.lificonsortium.org/index.html>



8.1.2.2 Stollman BlueHDP+USB dongle

This dongle can simply be used to add Health Device Profile (HDP) functionality to any PC with standard USB slot as there is no Bluetooth stack required on the PC. The Stollman²³ BlueHDP+USB dongle uses the Continua manager software CESL and works around of it enabling features such as embedded HDP and embedded Serial Port Profile. It uses the SPP to enable Continua compliant communication with agent devices but also proprietary communications. The dongle works over a virtual COM port to the application running on the PC which can use the Local Transport Protocol (LTP) to control the dongle and the data communicated.

8.1.2.3 Toshiba Bluetooth HDP stack and API

The Toshiba Bluetooth Stack for Windows has a HDP API layer that is implemented upon the (MCAP) IEEE 11073 Data Exchange Protocol layer and it (i.e. TosHdpApi) provides an interface to user applications for the HDP processing. It relies on the initial Toshiba Bluetooth stack which is only restricted to three types of HDP profiles: the blood pressure monitor (IEEE 11073-10407), the weighing scale (IEEE 11073-10415) and the cardiovascular fitness and activity monitor (IEEE 11073-10441).

8.1.3 Continuous Monitoring Devices

This section is divided according to device types relevant for the REACTION project. Each device type will follow with on market available and update devices.

8.1.3.1 Blood glucose meters

One of the major differences in control of glycaemic levels inside and outside the hospital is the fact that tight glycaemic control in hospitalised patients has to be provided by physicians and/or nurses. Achieving the goal of tight glycaemic targets requires extensive nursing efforts, including frequent bedside glucose monitoring, training to handle control algorithms or guidelines with intuitive decision taking and most importantly additional responsibility to prevent hypoglycaemic episodes. REACTION will deploy a closed loop feedback system to tight in-hospital glycaemic control (TGC) allowing diabetes experts to handle control algorithms with intuitive decision taking and fuse therapy instructions to healthcare physicians and/or nurses at the point of care.

²³ <http://www.stollmann.de/en/modules/bluetooth-products/bluehdp-usb.html>

Bayer Contour USB meter

The Bayer Contour USB meter lets you plug into a diabetes management. It makes it easy to access the knowledge the patient need to share with individual healthcare professional in order to modify any routine and better manage the diabetes. The Bayer Contour USB meter will let the patient gain the knowledge that can help to lower the HbA1c. This is made possible by a plug & play technology for instant access to patterns and trends and where the Bayer's new Glucofacts Deluxe software can help the patient but also the physician discover valuable insights and by that also get shared knowledge. The Bayer Contour USB meter kit includes the meter itself but also 25 test strips, Microlet 2 lancing device, 25 Microlet lancets, USB cable and a carrying case (Bayer Diabetes Care 2010).



MyGlucoHealth Meter

MyGlucoHealth²⁴ Meter is the first FDA (Food and Drug Administration (US)) cleared integrated Bluetooth enabled diabetic care product. It has a Bluetooth capability that allows for short range communication over secure wireless connection between devices, such as personal computers and cell phones. The user will by this feature get the luxury of digitally transmitting their daily readings through a real time online data collection network. Their clinicians can then get automatically updated on their patients. As a feedback the clinicians can intervene if the results uploaded by their patients require physician action.



The way it goes is that recorded results are automatically sent to MyGlucoHealth over a secure connection where the patients can track and chart their results, data, but also send information to their physician. The easy strip ejector minimizes time spent gathering a blood sample rapidly increases daily results. Testing results are available in as little as three seconds or less and requires an even smaller blood sample size (.3 μ L) compared to other meters. The MyGlucoHealth meter has an automatic coding of the test strips which makes it a more comprehensive diabetic testing system by giving the user the most control over the care of their diabetes but also by allowing for an enhanced communication between patient and doctor. Besides form giving simple operations and innovative functions, the MyGlucoHealth meter is claimed to be easy to use and easy to learn.

8.1.3.2 Weighing scales

Digital weighing scales are designed to measure weight of the patient and store this data. Some models also send this data via a communication protocol (usually Bluetooth) to an application hosting device or directly to a web server from which the patient himself/herself or the clinician can access the gathered data.

Tanita BC-590

The BC-590²⁵ is designed to transmit multiple readings, wirelessly, to a personal computer within seconds for an easy way to view and record fitness trends over time. This makes it a state-of-the-art technology to the health monitoring industry. The BC-590BT measures values from weight, body fat, body water, muscle mass, physique rating, daily caloric intake, metabolic age, bone mass and



²⁴ <http://www.myglucometer.com/>.

²⁵ <http://www.tanita.com>

visceral fat. It can handle up to 4 users, and was the first consumer scale to utilize Bluetooth technology. The Tanita weighing scale allows the user to save measurements on the internet via the new Microsoft HealthVault web page, or an intranet protocol.

LifeStar Scale Wireless Weight Scale

The LifeStar Scale²⁶ is a digital weight scale that enables precise weight measurement. This can be utilized in many disease management programs or fitness regimes. It is considered fast as an individual's weight is displayed clearly on the screen within seconds of stepping on the scale. Additionally, after weighing in, the results can be automatically transmitted via Bluetooth technology to the LifeStar PDA. Here it can be viewed and saved and even more, the data can be transmitted to the LifeStar Network where physicians may view patient data. The LifeStar Network provides additional remote patient monitoring services, privacy and data protection of patient information, and has also the ability to track vital signs data over time (LifeStar 2010).

Cardiocom TELESCALE

The Cardiocom TELESCALE²⁷ takes part of the industry telemedicine standard for CHF (Congestive Heart Failure) patient home monitoring management. The TELESCALE is an interactive home telemonitoring device integrated with a precision electronic scale from which patients each morning, use at home to answer a series of questions about their current symptoms and to measure their weight. This is referred to as their "Health Check" which provides two-way communication between patients and health care providers and can be customized by a physician for a patient's telecare and safety.

When the patient is using the TELESCALE, the Health Check data is automatically transmitted over the patient's telephone line directly to a computer server (OMNIVISOR) in the physician's office or to the CARDIO-PLAN nursing staff. The OMNIVISOR software analyses the patient's daily data and automatically identifies the patients in need of a follow-up call or any care plan adjustments. Cardiocom's so called "management by exception" approach is claimed to allow for an efficient and effective tele-management of large patient populations.



Alere DayLink Monitor

The Alere DayLink²⁸ monitor is a biometric measurement device that records a patient's weight and where the patient can answer to pre-programmed questions regarding symptoms of the chronic condition or co-morbidities that may be monitored. The patient answers the questions by pressing YES or NO keys. The participant's health information is then sent daily via a phone line to Alere's clinicians, which allows them to provide immediate guidance and/or alert the participant's physician if the symptoms require immediate attention (Alere 2010).

8.1.3.3 ECG meters

Electrocardiography (ECG) gives a trans-thoracic-over time collected interpretation of the electrical activity of the heart. The data is captured by detecting and amplifying the tiny electrical changes that are caused when the heart muscle depolarises during each heartbeat. Adequately, the ECG is measured on the skin surface. The in-hospital setting usually requires bed monitoring but there are some mobile ECG meters that can be used.

Zenicor-ECG

²⁶ <http://www.instromedix.com/HealtheKit.htm>

²⁷ <http://www.cardiocom.com/telescale.html>

²⁸ <http://www.alere.com>

The Zenicor-ECG²⁹ is a simple device to use for both patients and carers. It enables longer analysis periods and has been proven to have capabilities to diagnose temporary cardiac arrhythmia leading to improved and more accurate diagnostics. It is designed to be used of all kind of patients by simple placing thumbs on the device and take a measurement wherever the patient is thanks to its integrated mobile phone solution.

LifeStar ECG Wireless Cardiac Event Monitor

The LifeStar ECG is a lightweight and easy to use personal 1-leaded ECG event monitor that is intended for monitoring symptoms that may suggest abnormal heart rhythms. The LifeStar ECG communicates with the LifeStar PDA and the LifeStar Network and has the ability to track vital signs data over time (LifeStar 2010).

VitalJacket

Biodevices is a company that has developed products in the biomedical field with mainstream technology in order to seek the wellbeing and comfort for its users. The strategy is to develop and promote innovation, research and quality as fundamental factor in the production. One such product is the VitalJacket.

Biodevices hold partnership between innovative textile and miniaturized electronic components that to the analysis of physiological variables through a simple and remote method, has resulted in products with high quality. VitalJacket is a comfortable t-shirt that allows you to monitor continuously the heart wave up to 5 days, using miniaturized components through a non-invasive device. The product is composed by a t-shirt and a small electronic device box placed in a pocket. The VitalJacket is an intelligent wearable garment that is able to continuously monitor electrocardiogram (ECG) wave and Heart Rate (HR) for different fitness, high performance sports, security and medical applications. It either can store data on a SD memory card for posterior analysis in a PC or visualise it online using a Smartphone or PDA.



ePatch

The ePatch sensor is made in two designs. One is for recording of all measured data which are stored internally. The other sensor design is for long-term monitoring and constantly analysing data for the specific event in focus. Both types of sensors fit to any of the electrode designs. The highlights of the ePatch are that it has the possibility to stream or store data locally, include embedded software and algorithms, acquires up to one week of on-board storage, support real time synchronisation between sensors, support flexible power management, communicates over the ZigBee radio communication. It is also easy to clean and it is easy to snap on electrodes. The ePatch is one of the contributing sensors in the REACTION project and is under further refinement.



²⁹ <http://www.zenicor.se/>

HealthFrontier ecg@home

The ecg@home³⁰ is HealthFrontier's newest innovation for the web-enabled electrocardiogram (ECG) technology. It supports numerous connectivity features, including data transmission through USB, Bluetooth, or via the telephone line. The ecg@home is a powerful ECG solution for any healthcare environment. It is a single lead ECG event recorder that can record, and store an ECG tracing using the patented built-in electrodes but also record important ECG parameters which can be measured (e.g. heart rate, deviation of the ST segment of the wave, duration of the QRS complex, and abnormalities of the T-wave, T-Neg and Arrhythmia).



The procedure of the ecg@home is that it only acquires 10 seconds of Lead (I) using two thumbs, or Lead (II) using one thumb and an external lead placed on the left leg, or any peripheral Lead, such as V5, using the thumb and the optional external electrode. The ecg@home is powered by an IT backbone known as the Remote health Monitoring System (RHMS) which is HealthFrontier's web-enabled software application that automatically receives, stores and forwards incoming ECG scans to a patient's

Electronic Medical Record. By doing so, it eliminates the need for paper printouts.

8.1.3.4 Blood pressure monitors

Blood pressure (BP) is the pressure that is exerted by circulating blood upon the walls of blood vessels. BP is plainly one of the principal vital signs. During each heartbeat, BP varies between a maximum (systolic) and a minimum (diastolic) pressure and the mean BP, due to pumping by the heart and resistance to flow in blood vessels, decreases as the circulating blood moves away from the heart through the arteries. A blood pressure meter is a device used to measure the blood pressure, comprising an inflatable cuff to restrict blood flow, and a mercury or mechanical (i.e. later analogue to digital) manometer to measure the pressure.

Bluetooth Blood Pressure Monitor Wrist Type (HPI-108)

This BP wrist monitor uses a Bluetooth mobile phone or a PDA that can send command to the blood pressure monitor to start measuring blood pressure (Systolic / Diastolic) and pulse from the wrist. The measured results can then be transferred to the PDA or mobile phone through Bluetooth and where these immediately can display the progress. It is also possible to automatically send a SMS to any programmed number (physician or caregiver) when the measure result is over some setting value.

Other features that come with the blood pressure device are a statistical graph and a fuzzy logic measurement system where a high accuracy for up to 80 measurements with date and time eases recording and reviewing. It also gives an average of all records and a completely automatic inflation and deflation that provides convenience for the home blood pressure monitoring³¹.



LifeStar BP Pro Wireless Blood Pressure Monitor

The LifeStar³² BP Pro wireless blood pressure and pulse rate monitor is an advanced device for measuring and assessing hypertension. The LifeStar BP Pro also (like the LifeStar Weighing scale) communicates with the LifeStar PDA and the LifeStar Network. After

³⁰ <http://www.healthfrontier.com>

³¹ <http://excelec.en.made-in-china.com/product/mbQJBCTUYWhy/China-Bluetooth-Blood-Pressure-Monitor-Wrist-Type-HPI-108-.html>

³² <http://www.instromedix.com>

performing a test, the results are automatically transmitted via Bluetooth to the LifeStar handheld device, where it can be viewed and saved and as previously mentioned even transmitted to the LifeStar Network, where physicians may view the patient data.

Omron's HEM-790IT

Omron's HEM-790IT features Omron Health Management Software which helps patients to track their progress to a better blood pressure health. This monitor detects advanced diagnostics including morning hypertension and irregular heartbeat and monitoring these important factors with the Omron's software allows the patients to share valuable information with their physicians online.

The HEM-790IT has been tested, evaluated and proven to meet the rigorous safety and accuracy standards set by several independent organizations (HEM790IT 2010).



8.1.3.5 Pulse meters

A pulse meter, or a heart rate monitor, is a device that measures BPM (Beats Per Minute), i.e. the amount of beats that the heart makes per minute. Digital pulse meters can be placed around the chest, the wrist or the finger in order to collect data.

LifeStar Oxy Pro Wireless Pulse Oximeter

The LifeStar Oxy Pro is another product from LifeStar. It is an easy-to-use oximeter for measuring both oxygen saturation levels in the blood and the pulse rate. It displays the medical data on the LifeStar PDA where oxygen saturation and pulse rate averages with the maximum and minimum measurements.

Throughout the measurement, the results are automatically transmitted via Bluetooth technology to the LifeStar handheld device and the functions that follow are the same as previously described in chapters 0 and 0 (LifeStar 2010).



Alive Pulse Oximeter

The Alive Pulse Oximeter is a wearable medical device that uses wireless technology. It reads oxygen saturation data from a sensor on the finger or earlobe, and transmits the data via Bluetooth to a mobile phone, PDA, laptop PC, or other Bluetooth-enabled device that can act as AHD. The pulse oximeter can transmit the data in real-time or locally store the data for later download, if so required.

The data received from the Alive Pulse Oximeter³³ can be displayed on the oximeter's display. But it can also use the transmitted data for telemedicine applications or be transmitted in real-time to a central monitoring centre over the internet. The Alive pulse oximeter is well-suited for remote respiratory monitoring, e.g., for remotely monitoring patients receiving home oxygen therapy. The device is also suitable for home sleep apnoea screening, as the wireless technology provides a more comfortable environment for patient during sleep (AlivePulseOximeter 2010).

Nonin Avant 4000 Bluetooth Wireless Pulse Oximeter

The Nonin Avant 4000 System³⁴ with Bluetooth wireless technology provides freedom from wired connections while ensuring reliable and secure transfer of patient. This lightweight

³³ <http://www.alivetec.com>

³⁴ http://www.turnermedical.com/Nonin_Avant_4000_wireless_pulse_oximeter.htm



wrist-worn patient module wirelessly sends data to a small table top display and by that it improves patient mobility and reduces bedside clutter.

The highlights with this product is that it uses Bluetooth, is light and comfortable, has high power (33.5 hour memory and 10 meter signal radius), easy to use, customisable alarms, secure by data encryptions and efficient as the batter life is about 120 hours for patient module and 18 hours for the oximeter.

PM-50 Pulse Oximeter

PM-50³⁵ is a miniature, lightweight device designed exclusively for spot-check monitoring of SpO₂ and pulse rate. It weighs less than 200g, is easy to carry and easy to store. Deploying this pulse oximeter gives efficiency when performing intermittent monitoring of a wide range of patients (PM50 2010).

The PM-50 is also easy to maintain as it requires just four AA batteries for up to 15 hours of run-time. The features of the PM-50 are that it is suitable for adult, paediatrics, and neonatal patients, but also as it enables spot-check monitoring of SpO₂ and pulse rate and automatically updates the data every second. The device is made as by a miniature design that offers an impressive lightweight device making it easy to use on the go. Backlit LCD prominently displays SpO₂ and pulse rate readings accompanied by a pulse signal strength. Additional useful indicators shown on the LCD include patient ID, low power indicator, data storage indicator, error condition and standby mode. The PM-50 also give helpful prompts, including memory full, ID storage full, low battery and general error conditions, allow for simple and quick troubleshooting. The memory supports storage of 200 data records for a maximum of 100 patient IDs and is connective by plugging it to a PC using a standard communication cable for downloading and printing trend data.



8.1.3.6 Combo devices

This chapter deals with those devices that are capable of measuring and processing more than one physiological source at the same time.

MDKeeper

The MDKeeper³⁶ is an effortless, uninterrupted vital signs by which the elderly or chronically ill can maintain a normal active lifestyle without being confined to their homes or making frequent visits to their doctor. MDKeeper integrates unique, powerful biosensors into a lightweight wearable device where it can monitor multiple vital signs (such as pulse rate, 1-lead ECG and blood oxygen saturation level) without discomforting users. By using its proprietary integrated expert system, MDKeeper can store and analyse patient data or transmit the data to a remote



³⁵ <http://www.mindray.com/en/products/10.html>

³⁶ <http://www.aerotel.com/en/products-solutions/lifecare-mobile-solutions/mdkeeper-innovative-wristop-vital-signs-mo.html>

medical centre for further analysis and care, via its built-in Siemens Wireless Module.

MDKeeper can communicate with remote hospital information systems and integrate its data into existing and emerging telehealth applications, EPRs and other online data analysis and clinical decision support systems.

Fitbit

The Fitbit³⁷ accurately tracks burned calories, steps taken, distance travelled and the sleep quality. The Fitbit contains a 3D motion sensor by which it tracks the motion in three dimensions and converts this into useful information about user's daily activities.



The Fitbit can record detailed daily data for 7 days and as summarised daily data (daily steps, calories and distance) for some 30 days. When the Fitbit is within range of its base station (computer), it will automatically upload any stored data that it has recorded and if the user walks within 5 meters of the base station the data will be automatically uploaded to the Fitbit website (FitBit 2010).

BioHarness

BioHarness BT³⁸ couples the pioneering smart fabric sensor technology of garments with the power and ubiquity of Bluetooth. BioHarness BT enables the capture and transmission of comprehensive physiological data on the wearer and transmits the data via mobile and fixed data networks. This enables a genuine remote monitoring of human performance and condition in the real world. The BioHarness product capabilities are that they have a SDK available from which applications can be built to monitor heart rate, breathing rate and relative depth, IR skin temperature measurement, activity measurement via 3D accelerometer, posture analysis, remotely configure thresholds and to stream, sample or threshold data transmission modes over a cellular data network. The SDK is available on request. The kit is an excellent way to integrate the BioHarness into other third party software (BioHarness 2010).

Intelesens VS100

The Intelesens³⁹ VitalSens 100 (CE approved) patch based Bluetooth Vital Signs Monitor. Intelesens is a spin out from the University of Ulster where there is a strong long term relationship with three leading academics which should ensure the continued identification and design of Intelesens products. The VitalSens provides wireless ECG, heart rate, skin surface temperature and motion for any existing or new product. It is designed to be rapidly integrated into medical devices or systems and can be configured for two different modes of data collection: periodic data transfer via Bluetooth (frequency configurable (default: 15 minutes) or live data streaming via Bluetooth transmitted).

8.2 Continua compliant devices

Continua⁴⁰ certified devices available for many physiological measurements were at first internal watch 16th May 2010 listed in Table 1. Unfortunately, this list has to this date (29th February 2012) *not* been updated with new medical devices (software and hardware accessories excluded).

³⁷ <http://www.fitbit.com>

³⁸ <http://www.zephyr-technology.com/bioharness-bt.html>

³⁹ <http://www.intelesens.com>

⁴⁰ www.continuaalliance.org

Device	Manufacturer	Model	Transport
Blood pressure	A&D	UA-767PBT-C	Bluetooth
	Cypak	CPX186 Continua convertor cable	USB
	Omron	Home blood pressure	Bluetooth
Glucose meter	Roche	Accu-Check Smart Pix	USB
Pedometer	Omron	Pedometer with Bluetooth docking	Bluetooth
Pulse oximeter	Nonin	PalmSAT 2500	Bluetooth
	Nonin	Onyx II 9560 Fingertip	Bluetooth
Weighing scales	A&D	UC-321PBT-C	Bluetooth
	Omron	Weighing scales with body composition	Bluetooth

Table 1 Available Continua agents.

(AND Medical 2010), (Cypak 2010), (Omron 2010), (Nonin 2010).

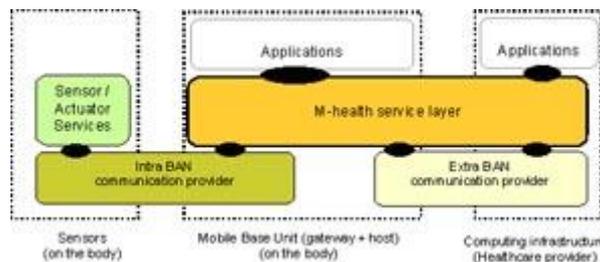
8.3 Central BAN/PAN Units

BAN/PAN units are hard to distinguish as they often play a role in larger solutions. But some are available on the market and they are described here.

8.3.1 HealthService 24 (eTEN-517352)

This project deals with the fact that there today is no concise mobile monitoring service available in Europe. It aims to bridge this gap offering a viable mobile health care service permitting healthcare professionals to remotely assess, diagnose and treat patients whilst the patients are free to continue with daily life activities. The HealthService24 allows patients and non-patients to monitor their physical condition and obtain advice and information at any place and moment. Hence the service will enable patients to be fully mobile. For this they offer a system architecture for BAN.

This means that collecting and transmitting vital signal measurements as part of the healthcare service platform developed in the MobiHealth project will provide feasibility for integration in the clinical process and market viability. The dotted square boxes indicate the physical location where parts of the service platform are executing. The rounded boxes represent the functional layers of the architecture. The M-health service platform consists of sensor and actuator services, intra-BAN and extra-BAN communication providers and an M-health service layer. The M-health service layer integrates and adds value to the intra-BAN and extra-BAN communication providers masking applications from specific characteristics of the underlying communication providers.



9 Patient Apps

Global app stores have an upload of programs designed to help people monitor their health by using a smart phone. Below we list a selected set of examples of apps for both iPhone and Android smart phones, to illustrate what is available for diabetes patients today.

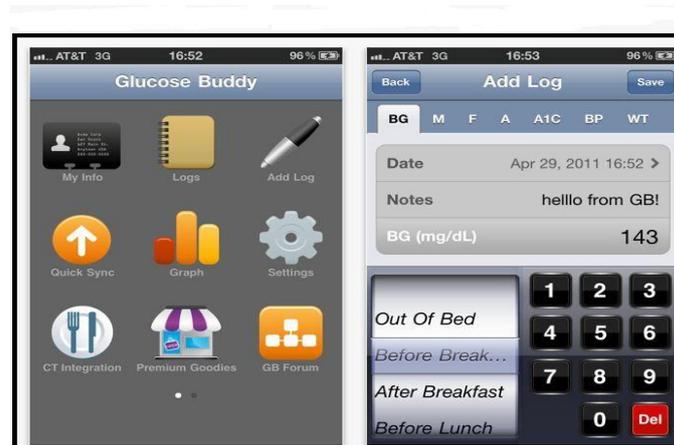
Although very little has been reported so far about the long-term usefulness of such apps for diabetes patients it is clear that the REACTION platform needs to relate itself to these apps, since it is likely that many diabetes patients, especially younger will use one of them. For instance if you already have entered data about meals eaten into your iPhone app, you would find it very cumbersome if you have to do it once again in a different user interface to get it into REACTION.

Bant⁴¹

Bant is an interface application to enter data in an easy way for diabetes patients to allow them to record and store blood glucose reading when they are on the move



Glucose Buddy App⁴²



The Glucose Buddy App allows the user to log Blood glucose, Medication, food and exercises. Logging high and low blood sugar symptoms and adding notes will make the personal health record more complete. Example of notes might be: "This is a fasting blood sugar log" OR "Blood sugar elevated because of high Carb lunch".

⁴¹ <http://bantapp.com/>

⁴² <http://www.glucosebuddy.com/>

Insulin Dose Advisor



By using Insulin Dose Advisor⁴³ user gets personal dose-suggestions. The user/patient simply enters glucose level, Carbohydrate intake and insulin dosages during several days/weeks and IDA-ControlWizard starts to advise person on the insulin dose that is most likely to result in good blood glucose level within the next 2-4 hours.

IDA-ControlWizard stores your data on your device. Regularly backup your data to the online server is located in a state of the art, class A, data centre. By using IDA-ControlWizard you agree that anonymous data may be used for scientific research and/or to monitor the quality of the application’s algorithms. No personal information is transferred to the database on the online server and no personal information is used in the process.

iBGStar® Diabetes Manager App

In order to be more independent, living with diabetes, iBGStar Diabetes Manager App⁴⁴, accessed from an Apple iPhone or iPod touch, which can be use whenever and wherever. iBGStar connects simply to iPhone or iPod touch, launch the device and app which blood glucose readings will immediately and automatically be transferred from the blood glucose meter to the app. Test result stored on the meters memory and visualised in charts of the iBGStar Diabetes Manager App can analyse trends and variation to proactively managing diabetes even on the go.



⁴³ <http://www.knowledgequizz.com/cw/cw.html>

⁴⁴ <http://www.bgstar.com/web/ibgstar/app>

Each scorecard (record) has divided to the three parts or “Tabs” of information. Glucose Tab, Carb Tab, Insulin Tab. The date and time is displayed on all three tabs of the scorecard to help identify the data clearly. It could also be added an unlimited number of pre-defined or custom notes to each of scorecards.

Blood Glucose Diary

The Blood Glucose Diary is the first app under this platform, aimed in helping you in keeping a tab over your blood glucose levels and having it tightly integrated with Google Health as well as Maestros's own eHealth24x7.com Platform, you get a complete control over your Glucose, Food intake and Activity schedules.



My Blood Glucose & HbA1c

Keeps track of Blood Glucose and HbA1c. You can select between mg/dl or mmol/l and a category (dinner, lunch, random, etc). - Visualize the data in an item list or a linear chart. Export data option to:CSV attachment, Plain text



OnTrack Diabetes

Manage diabetes better by tracking blood glucose, medication and other values.

OnTrack is an application to help diabetics manage their diabetes by tracking various items such as blood glucose, food, medication, blood pressure (BP), pulse, exercise and weight.

Features include:

- easy to use interface makes it a snap to add new entries
- Add multiple entries simultaneously, for example add glucose and medication at one time quickly and easily
- a variety of detailed graphs and reports
- a detailed log book with tables and graphs suitable for sharing with your doctor
- Supports both US (mg/d) and international (mmol/l) glucose units.
- export your data in a variety of non-proprietary formats including CSV,HTML,XML

- annotate each entry with a category (breakfast, lunch, dinner, etc)
- customize categories, medications, exercise types and more by adding, removing or renaming as desired
- automatically have OnTrack select the right category for new entries based on time of day
- activate reminders on new entries, for example remind yourself to test two hours after eating food.
- Your data is your data, backup and restore as needed and even move it from one phone to another



Cellnovo

Cellnovo⁴⁵ has launched what seems to be the world's only mobile-connected diabetes management system, and the start of the largest usability trial ever to investigate insulin pump technology for patients with type 1 diabetes. The trial will also be the first in which all clinical data is captured remotely, in real-time; using the mobile data connectivity of the Cellnovo system. The diabetes management system comprises an insulin pump that connects wirelessly to an intuitive 'app-based' touch-screen handset. The handset features an integral blood glucose monitor, an activity monitor and a mobile (GSM) data connection to a comprehensive web-based clinical management system. This means that their patients will be able to track and manage their diabetes; securely sharing all clinical information through the web so that they, their doctors, nurses and family members can ensure sustained and effective diabetic control.



⁴⁵ <http://www.cellnovo.com/Default.aspx>

10 Technologies for diabetes support

10.1 Introduction

The effective management of chronic diseases such as diabetes is a complex task. It involves various actors who perform a lot of different activities. A number of care models have been proposed which provide conceptual frameworks for service delivery. A summary has been published by the London Health Observatory [Arowobusoye and Furlong (2008)]. Activities are implemented in a distributive way while the necessary data and information come from an integrated and unified information space. A shared access is available from different activity spaces into the information space. The information space and the activity spaces together generate the integrated care space, which promotes the effective application of info-communication technologies and unites the participants into a virtual organization [Deutsch et al. (2009), Gergely (2011)].

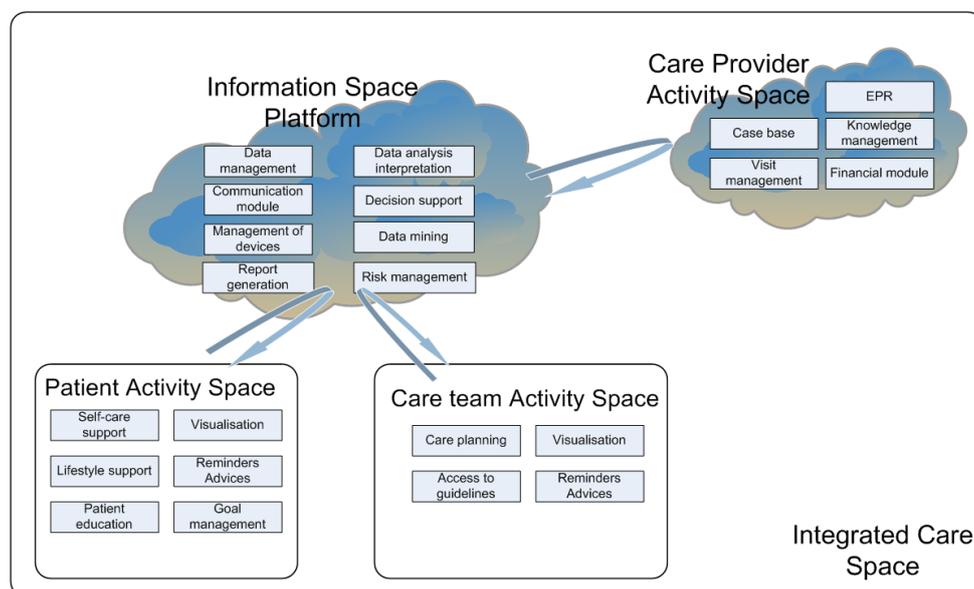


Figure 13: The integrated care space

ICT has the potential to support these activities in a variety of ways, e.g. by providing therapy recommendation to the physician and insulin dosing advices or reminders to the patients. There is a substantial amount of literature related to technological developments in diabetes care. In this section we inspect the recent advances from three points of view: which actors does it support; what kind of activities does it support and what kind of support services does it provide. We will focus on the role of technology from these points of view, and cite some examples from the scientific literature and commercial applications.

10.2 Actors

Chronic disease management requires the involvement of various actors in the care process:

- the patients (including their social environment: family members, friends – often called informal carers);
- the physicians (GP, specialist);
- other medical personnel (nurse, diabetes educator etc.);
- the healthcare provider organizations (e.g. hospital, primary care provider)

Every actor should be supplied with appropriate information in order to improve the effectiveness of their activity. Involving patients, i.e. self-management is important as most of

the necessary actions and problems arise between visits. With appropriate ICT support, the medical personnel can partially take over the physicians' role, so the latter can focus their efforts on the more complicated problems or cases. Note that the various health professionals form together the multidisciplinary care team. The healthcare provider organisation can use the collected data for management activities like reporting or financial planning.

Recently developed applications support one or more of these actors in performing their activities. Detailed examples will be discussed in the next two sections.

10.3 Activities

There are various activities related to chronic care. Most recent advances are reflected in the latest clinical guidelines [see e.g. Paulweber (2010); Sibal (2009) and Funnel (2010)]. Guidelines set the recommended activities both for health professionals (e.g. perform yearly eye and foot examinations) and patients (e.g. self-monitoring or dietary recommendations).

10.3.1 Care team

The management of diabetic patients should rely on a personalized care plan. It is the result of the therapy planning activity and it records the prescriptions and goals of the. Besides pharmacological therapy, lifestyle is an important aspect of the care of patients with chronic diseases. In many cases, lifestyle interventions like diet modification or increased physical activity can be the first therapy choice for patients with type 2 diabetes, but it supplements other therapy types as well. Detailed recommendations for therapy selection can be found in guidelines and consensus statements, e.g. Sibal (2009) and Nathan et al. (2009). Evidence-based literature is another important source of the most recent scientific results. Finding the most adequate information in this huge knowledge base can be a difficult and time-consuming task. This causes that guidelines are not always appropriately used in clinical practice. ICT solutions, for example decision support systems can facilitate this process. Garg et al. (2005) provide a systematic review of the effects of clinical decision support systems. There are also attempts to standardize computer-interpretable guideline representation. De Clercq et al. provide a review of these methods. Another example is Thomson Reuters' Micromedex which provides a rich collection of evidences, recommendations and drug information. On-going education is also an important part of the management of patients with chronic diseases. Thus the care plan should describe treatment, lifestyle, self-monitoring and education goals.

The care team should continuously monitor the patient's status. This means at least regular visits where the patient's physiological status and preferably also the psychological-mental status is assessed and evaluated, and if necessary, the care plan is updated. The recommended frequency of reviews is described in the guidelines, e.g. the NICE Guideline for the management of type 2 diabetes [Sibal (2009)]. With the advance of technology, especially telemonitoring, the patient is able to provide information about his/her health status between the visits as well. Paré et al. (2007) published recently a review of home telemonitoring applications for some chronic diseases, including diabetes. The study concludes that home telemonitoring of chronic diseases seems to be a promising patient management approach that produces accurate and reliable data, empowers patients, influences their attitudes and behaviours, and potentially improves their medical conditions. More details of data collection methods and data communication are discussed in the next section. The competent members of the care team can evaluate these information and perform appropriate actions if necessary e.g. organize a visit or provide recommendations to the patient. If this process is properly assisted by ICT, it can be performed by nurses and only the most difficult cases need to be referred to the physician. This support includes visualization and analysis of the data and decision support.

As chronic diseases are usually life-long conditions, patients need proper mental and psychological support. For example, they often suffer from depression or anxiety which is associated with decreased quality of life [Goldney et al (2004), Kruse et al. (2003)]. Moreover increased stress may cause hyperglycaemia which is the first step towards complications if it is not properly treated. Thus they need to learn how to decrease stress level or cope with the disease. Supporting these activities, together with patient education, should be the task of specialized members of the care team. Technology is able to substitute some of these: e-Learning for example can be used for educating patients. Intelligent applications providing personalized advices may also be useful.

10.3.2 Patient

The implementation of the care plan is the task of the patient, often supported by his/her social environment. This is called self-management as it includes not just taking medications, but the complex management of the patient's lifestyle, including among others proper food choices, physical activity and stress management. This requires a certain level of knowledge and health literacy from the patient. Therefore on-going learning is a key point in chronic disease management.

Patients face a lot of various risk factors which may cause aggravation of the disease or development of complications if they are not properly managed. An important prerequisite of successful risk management is regular monitoring which helps to detect problems in time. Some research results state that the benefit of intensive blood glucose monitoring for patients not using insulin seems rather weak: see e.g. the work of Clar (2010); Davidson (2010) and Welschen (2005). However, for people with diabetes who do not use insulin, personalized structured education may be the missing link to deriving benefits from SMBG. Polonsky et al (2011) argue that previous research has not considered structured SMBG with proper education, where participants are empowered with actionable knowledge on how to deal with different circumstances related to blood glucose variability. Clar (2010) also agrees with the view that proper actionable knowledge will result in SMBG benefits for people not using insulin or oral agents.

Technology is able to support this activity in a variety of ways. Self-monitoring is the most developed field: numerous monitoring devices and logbook software were developed. Some examples are presented in the next section. Patients may also be supported by therapy and lifestyle advices or reminders.

It is important for patients to have clear goals, being motivated to attain a predetermined level of performance, and having enough information to understand behavioural options to improve performance [Mulvaney (2009)]. It is best if the goal state is generated by patients and providers through collaborative goal setting.

10.3.3 Care provider

The care provider organization performs various management activities. These are usually not disease-specific activities, especially in primary care where the care teams provide care to patients with a variety of chronic and acute diseases. One example is visit management, which aims to optimally schedule patients, health professionals and possibly other resources like equipment. This could be a challenging issue. Gupta and Denton (2008) provide an overview of these challenges and opportunities.

Moreover, the care provider maintains a patient record which stores all of the medical data of the patients. These are nowadays almost exclusively electronic systems. Hippisley-Cox et al. (2003) compared paper-based and paperless patient records in primary care. They found that electronic records were easier to understand and were more likely to have at least one

diagnosis recorded, to record that advice had been given, and to record the specialty of referrals and the doses of prescribed drugs. Electronic records also contained significantly more words, abbreviations, and symbols. The data contained in the EPR can be transformed into cases, and the resulting case base can be used for case-based reasoning (CBR). The core idea of CBR is that when a new situation is similar to one or several old situations, the decisions taken and the knowledge contained in old situations provide a starting point to interpret or solve the new situation. Armengol et al. (2001) for example present the DIRAS system which aims to determine the risk of long-term complications of diabetes using CBR.

Another important activity is the maintenance of the organizations knowledge, mainly in the form of guidelines, pathways and evidence-based literature. They are typically paper-based or electronic documents. Finding the most appropriate information from these documents might be challenging. Advanced (semantic) search solutions are able to support this activity. Information retrieval methods from free text documents are described in a separate section. The use of computer-interpretable guidelines and decision support systems may also facilitate the use of this organizational knowledge (see also the previous section).

10.4 Services

Technological advances provide a variety of ways to support the actors in performing their activities. These include data collection, communication between the actors, decision support, data visualization and analysis, data mining and knowledge discovery. The last two functionalities are discussed in a separate section. The remaining of this section provides some examples of ICT solutions in diabetes care.

10.4.1 Data collection

The effective management of diabetes requires the collection and analysis of various data items. This includes not only clinical and laboratory test, but also self-monitoring which aims therapy, lifestyle and risk management as well: diabetic patients are encouraged to regularly monitor their health status, including blood glucose, weight or lifestyle parameters (diet patterns and activity levels). Self-monitoring provides large amounts of data. Traditionally, patients kept a paper-based logbook which was in the best case reviewed by the physician at regular visits. With the advance of technology, numerous electronic logbook solutions were developed and it became the most mature field of commercial diabetes applications.

Chomutare et al. (2011) provides a review and in-depth analysis of the features of mobile diabetes applications. They inspected more than 100 applications. The analysis included application from online vendor markets (online stores for Apple iPhone, Google Android, BlackBerry, and Nokia Symbian) and literature. In this study, blood glucose monitoring was a selection criterion; therefore all of the inspected applications implemented this functionality. Tools for tracking insulin or other medication were present in 89 (65%) of the applications. Just over half of the applications had some form of diet management, either by tracking carbohydrate intake or by providing meal suggestions. Physical activity and weight tracking had 55 (40%) and 53 (39%) applications, respectively. The study also shows that most online market applications are based on manual entry of data.

The screenshot shows a data entry interface for 'Log for Life'. It includes input fields for:

- Glucose: mg/dL
- Carbs Eaten: Carbs
- Meds: Units of **Novolog** (with a dropdown arrow and a plus sign)
- Exercise: Minutes
- Weight: lbs
- Time: 9:57 AM
- Notes:

 At the bottom, there are six circular icons representing the data categories: Glucose (red), Meds (blue), Carbs (green), Exercise (yellow), Weight (purple), and Notes (orange). Below these icons are three buttons: 'Save', 'Save and Add Another', and 'Cancel'. A text box at the bottom right states: 'You can also log via email from your desktop or cell phone by sending messages to abcd12@inbox.logforlife.com. [Learn More about Email Logging](#)'.

Figure 14: Data entry screen from Log for Life⁴⁶

Mulvaney (2009) argues that self-reporting of physiological or lifestyle parameters are subject to issues with memory and response bias. Recent efforts to measure self-management and other health behaviours in real time using mobile technologies are promising. Recent research has identified for example the value in using cell phone cameras to document food choices and quantities. Many mobile systems provide assessment that is closer in time and proximity to the actual barriers to self-management but still rely on self-report. However, any automation or mobile monitoring of health behaviours will make the integration of adherence data into clinical management much more feasible.

The study of Chomutare et al. (2011) also revealed that 16 (62%) of the 26 applications found in the literature used wireless (Bluetooth, ZigBee, or Wi-Fi) automatic data acquisition. In addition, some desktop applications support the communication with certain types of glucometers via cable, infrared or Bluetooth connection. ALL has also developed an infrared device which is able to retrieve glucose measurements from some glucometers.

It should also be considered that elderly patients are often not familiar with computers or mobile devices, therefore automated methods might be preferred. Recent research aims to develop devices (glucometers, weight scales, blood pressure monitors) which automatically submit data to a central database. However, monitoring lifestyle parameters is still not straightforward in such a way. Keeping a detailed daily log requires much efforts and manual input. These parameters are most commonly assessed using questionnaires. They may provide a good general view of a certain time period, but usually not able to measure day-to-day details.

10.4.2 Data communication

The communication of the collected data about health status, therapy and lifestyle between users (e.g. patients and carers, health professionals) is a well-developed functionality. Patient monitoring software which is web-based or can be synchronized with a central database has the advantage that the data are accessible by authorized users from anywhere. Health professionals and informal carers are able to view and analyse the patient's actual health status and can contact the patient in case of a problem or provide advices. A component for synchronizing with PHRs or Web portals was present in 40 (29%) of the applications evaluated by Chomutare et al. Otherwise at least reports or graphs can be

⁴⁶ <https://www.logforlife.com>

printed or emailed to health professionals. About 60% of the analysed applications provided some kind of communication feature.

For example, GluCoMo⁴⁷ provides a communication platform for patients, health professionals and healthcare providers. With GluCoMo mobile applications, data on patients' mobile devices is kept up-to-date at a central database through 3G or Wi-Fi, and is made available for the patient-authorized doctors to track and analyse. Doctors can set up automated alerts, give advice based on the latest data, and schedule medical check-ups directly with patients through their mobile phones using GluCoMo or other mobile phone alerts. Apart from allowing scheduled and real-time communication between doctors and patients through mobile phones, the system also provides an online portal for participating doctors, hospitals and patients to manage their own profiles and activities. This allows hospitals to better manage their doctor-patient ratios. Inter-hospital communication is enabled via the underlying telematics platform, allowing doctors to easily share advice, medical opinions and diagnostics.

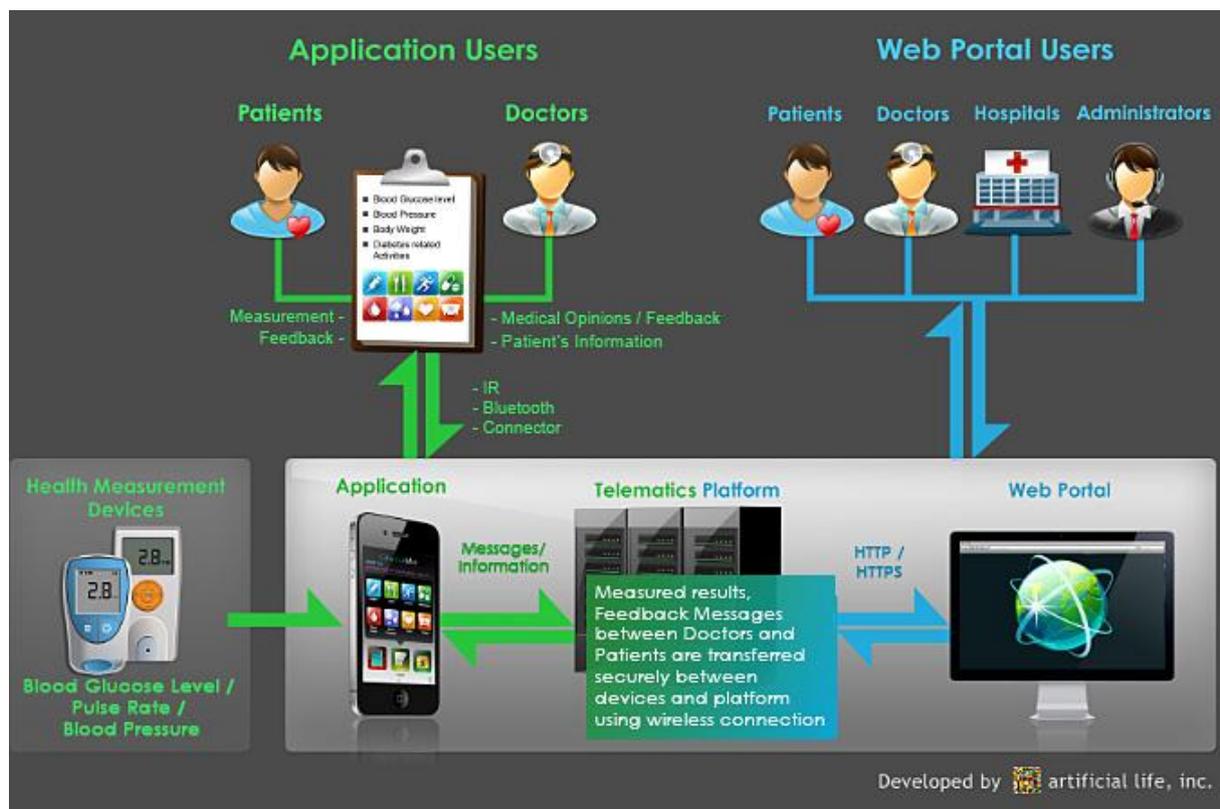


Figure 15: Architecture of GluCoMo

10.4.3 Visualization and data analysis

Telemonitoring provides huge amounts of data which may be difficult to interpret. It is not enough to detect high or low values, it is also necessary to analyse the possible causes to be able to determine the necessary interventions. Pearson and Bergenstal (2001) suggest that identifying patterns in blood glucose levels and lifestyle can help to optimize glucose control. However, current applications support data analysis and pattern management only by visualizations and the calculation of simple statistical parameters. Figure 16 provides an example of blood glucose report.

⁴⁷ <http://www.glucomo.com/site/en/about>



The Diabetes Pilot application as another example for visualization and data analysis provides the following report types⁴⁹:

- Average BG by Category - Shows average glucose organized by category
- Average BG by Hour - Shows average glucose as an average for each hour of the day
- Average BG by Month - Shows average glucose by month
- Glucose Graph - Graphs individual glucose readings over time
- Glucose 24 Hr Overlap - Graphs several days of glucose readings overlapped on a single 24 hour graph to help identify daily patterns in the data.
- Glucose Monthly Overlap - Graphs several months of readings overlapped on a single 1-month graph to help find monthly patterns in the data
- Record Listing - Lists the records in a manner similar to how they appear on the My Records page.
- Record Listing (Plain) - Lists the records in a manner similar to how they appear on the My Records page in a more plain format suitable for export to spreadsheets other programs.
- Record Grid - Shows the records in a grid format organized into columns for each record type

⁴⁸ <https://sugarstats.com/tour/>

⁴⁹ <http://www.diabetespilot.com/desktop/docs/reports>

- Logbook/By Category - Shows the records in a "logbook" grid format organized by category
- Meal Listing - Lists the foods and nutritional content in the meal entries
- Meal Listing (Plain) - Lists the foods and nutritional content in the meal entries in a format suitable for export to spreadsheets and other programs.
- Daily Food Summary - Summarizes food intake by day
- Medication Totals - Shows a total of the medications entered for each day
- Exercise Totals - Shows a total of the exercises entered for each day
- Glucose by Range - Shows the number of glucose measurements in target range, above "high" limit, and below "low" limit. These ranges can be set in the preferences window
- Recent BG Averages - Shows average glucose for various time periods.
- Blood Pressure List - Lists blood pressure readings

Indeed, well-designed charts and reports might help to identify patterns, but it needs experience to properly interpret them. It is more useful if the software automatically performs the analysis, list the identified patterns and recommends interventions. More details about data analysis and data mining are provided in a separate section. Automated analysis also saves time, and the patients who need intervention could be more easily identified. Results of this analysis can also be used by patients, but only if it is supported with proper advices. Without them the patient may not know what to do, so it may cause only confusion or anxiety. This kind of support provides a good opportunity for personalized and on-demand education.

10.4.4 Decision support

Interest in telemedicine is growing rapidly. Thanks to engineering advances in telecommunications, software, and human factors, the core technologies for the practice of telemedicine for diabetes and other diseases are rapidly advancing. In spite of obvious benefits from utilizing real-time transmission of accurate organized and analysed data, telemedicine has not been widely adopted. Klonoff (2009) argues that the blame is usually assigned to a lack of reimbursement and lack of physician training in using this approach. But these are not the only reasons behind the slow adoption. Additionally, telemedicine in and of itself does not solve the resource problem of limited health care professionals and specialists for the vast multitude of patients with diabetes. While telemedicine can enable remote access to patient data, it does not increase the clinician's ability to evaluate more patients within a fixed time period. When a general practice is already overbooked with patients, with many more waiting in line, there is little perceived need to increase workload via telemedicine. Until telemedicine applications can help solve this basic resource problem, their adoption into routine clinical practice will be slow.

Most telemedicine programs are actually telemetry systems that transmit physiologic data and history data, but they provide no recommendations or decisions [Farmer et al (2005)]. In order to elevate telemetry to true telemedicine, it will be necessary to incorporate decision support into the telemedicine system. Without decision support, clinicians are no more empowered to provide recommendations for acute care in a remote setting than they are in a face-to-face setting, it only saves travel costs. Furthermore, in a telemetry care setting, clinicians may be hindered by a lack of direct contact with a patient because they cannot glean information from a physical examination or nonverbal communication.

With the addition of decision support to a telemedicine system, transmitted medical information can be instantly distilled into robust treatment recommendations. When such recommendations are automatically generated, this process will save time for the clinician and provide superior care for the patient in an acute care setting or a follow-up visit setting compared to a care delivery system where the clinician has to spend time thinking about the situation, researching best practice guidelines, and constructing an individual treatment plan. A computerized treatment plan should always be considered as a recommendation and not an order. Any decision support recommendation might possibly require modification by the clinician because of factors that are not accounted for in the decision support software. An ideal decision support recommendation will incorporate all the available uploaded data in real time and usually come very close to a recommendation that a clinician will want to order.

Kawamoto et al. (2005) evaluated the features of clinical decision support systems in order to identify those critical for improving clinical practice. They found that the most important features are (a) provide decision support automatically as part of clinician workflow, (b) deliver decision support at the time and location of decision making, (c) provide actionable recommendations, and (d) use a computer to generate the decision support. A common theme among all four features is that they make it easier for clinicians to use a clinical decision support system. For example, automatically providing decision support eliminates the need for clinicians to seek out the advice of the system, and the use of a computer system improves the consistency and reliability of the clinical decision support system by minimising labour intensive and error prone processes such as manual chart abstractions. As a general principle, then, the findings suggest that an effective clinical decision support system must minimise the effort required by clinicians to receive and act on system recommendations.

Decision support is also useful for patients regarding their therapy or lifestyle, but this is provided mainly by research application. One exception is insulin dosing decision support for patients treated by insulin: some commercial software solutions (e.g. SiDiary⁵⁰) provide basic calculators for insulin dose. Albisser (2005) reported a software for insulin dose calculation which takes lifestyle aspects into consideration, namely changes in meals (carbohydrate content), planned physical activities and stress levels. Registered health professionals are able to personalize parameters (e.g. insulin sensitivity) and monitor the patient's data.

10.4.5 Patient education

Patient education is an important aspect of mental support of patients. According to Chomutare et al. (2011), only 27 of the examined applications had an educational module, and seven of these provided personalized education, tips, feedback, or advice. There are numerous web pages providing information or educational materials about diabetes, but it is not an easy task for patients to select the most appropriate ones in respect of subject and level of difficulty. Complete e-Learning courses are also available, but neither these are personalized. It is useful to perform some kind of knowledge assessment to identify the gaps and provide education which is aligned with the patient's actual needs. A computer programs which suggest educational resources taking into account their physiological and psychological-mental state might be very useful. Alternatively, effective semantic search solutions may facilitate the selection of most appropriate resources.

McKay et al. (2002) identified three functions of patient education: increasing knowledge, providing skills training, and enhancing social support. Knowledge transfer is fundamental, but not sufficient in its own. Effective self-management training also helps participants to set personal goals and provides them with feedback and diabetes problem-solving and coping skills needed to deal with the ever-changing challenges to self-care. Another important but often overlooked function of diabetes education is to provide social and emotional support.

⁵⁰ <http://www.sidiary.org>

The Diabetes Network (D-Net) project reported in this paper provided personalized self-management support (coaching) and peer support through internet. The results are promising as the researchers reported significant improvements, especially on dietary behaviour. However, this project employed human professionals for providing support. They might be substituted at least partially with intelligent computer agents as well.

Mulvaney (2009) also suggests that teaching the skills necessary for successful self-management like identification of problems, planning solutions and overcoming barriers is important.

10.4.6 Compliance and concordance support

Several terms are used to describe the patient's behaviour regarding medication taking and other health advices. Compliance is defined as the extent to which a patient's behaviour in terms of taking medication, following diets, or implementing lifestyle changes coincides with medical or health advice. According to the World Health Organisation's 2003 report between one third and a half of medicines prescribed for long-term medical conditions are not taken as directed. If we assume that the prescription was appropriate for the individual patient, then this level of non-compliance with prescription recommendations is a concern for those providing, receiving or funding healthcare because it not only entails a waste of resources but also a possible missed opportunity for therapeutic benefit. Thus we can conclude that it is an important challenge to increase compliance. Chen et al. (2009) for example propose a Mobile-phone based Patient Compliance System (MPCS) that can reduce the time-consuming and error-prone processes of existing self-regulation practice to facilitate self-reporting, non-compliance detection, and compliance reminders. The novelty of this work is to apply social behaviour theories to engineer the MPCS to positively influence patients' compliance behaviours, including mobile-delivered contextual reminders based on association theory; mobile-triggered questionnaires based on self-perception theory; and mobile enabled social interactions based on social-construction theory.

In the mid-1990s, the UK Department of Health and the Royal Pharmaceutical Society of Great Britain started a collaborative project that aimed to understand why patients did not take their medication, and to develop solutions to this problem. The resulting report, *From Compliance to Concordance*, was significant in the development of the concept of "concordance". Concordance encompasses the idea that the doctor and the patient are equals, and that the patient makes informed decisions. The doctor/patient relationship should be a partnership, in which time is taken to explain the illness in question – such as diabetes – and to explore what the patient understands and believes about the condition. Different treatment options available to the patient should be explained in such a way that the patient can understand them. According to the model of concordance there should be an open exchange of beliefs about medicines upon which both prescribing and medicine taking decisions may then be based. The key difference between compliance and concordance is that the former generally focuses on the behaviour of one person, the patient, whereas the latter requires the participation of at least two people.

As Clyne and Colin-Thomé (2008) argue, achieving concordance is not about the clinician giving up their power and authority but more about enabling the patient to share the power and authority to make treatment decisions, if they should choose to. It assists the patient to weigh up the pros and cons of a treatment decision. It can help both parties involved to structure their thinking, work out the most important factors from the patient's perspective and what the patient wants to do about them. With this approach patients become partners in their own care, and they are more likely to adhere to the agreed plan. The analysis of Montori et al. (2006) also concludes that greater involvement of patients in decision making may result in improved quality of life and physiological parameters.

Achieving concordance requires certain skills from both patients and health professionals. Patients need a basic level of knowledge and health consciousness. Proper education (supported with ICT) may facilitate the development of concordance. Professionals need specific consultation skills, e.g. to explain medical problems in such a way that patients can understand, taking into account the patient's knowledge and skills. Moreover they need to increase patient's involvement into the consultation and decision making. The NHS guideline about Medicines adherence (2009) discusses these skills and methodologies.

10.4.7 Generic technologies

There are several generic technologies which may support the effective realization of the above mentioned functionalities.

Service-oriented architecture is a popular technology to build complex systems. It allows to develop a flexible platform where new services can easily added and services can be reorganized to support new workflows and use cases.

Middleware technology is often used in a network environment to facilitate the communication between users, including human and machine actors. For example, connecting monitoring devices to the system is a typical feature of middleware. In addition the middleware may provide security services. The MORE middleware was developed in an EU project, and its use was demonstrated among others in a diabetes care scenario.

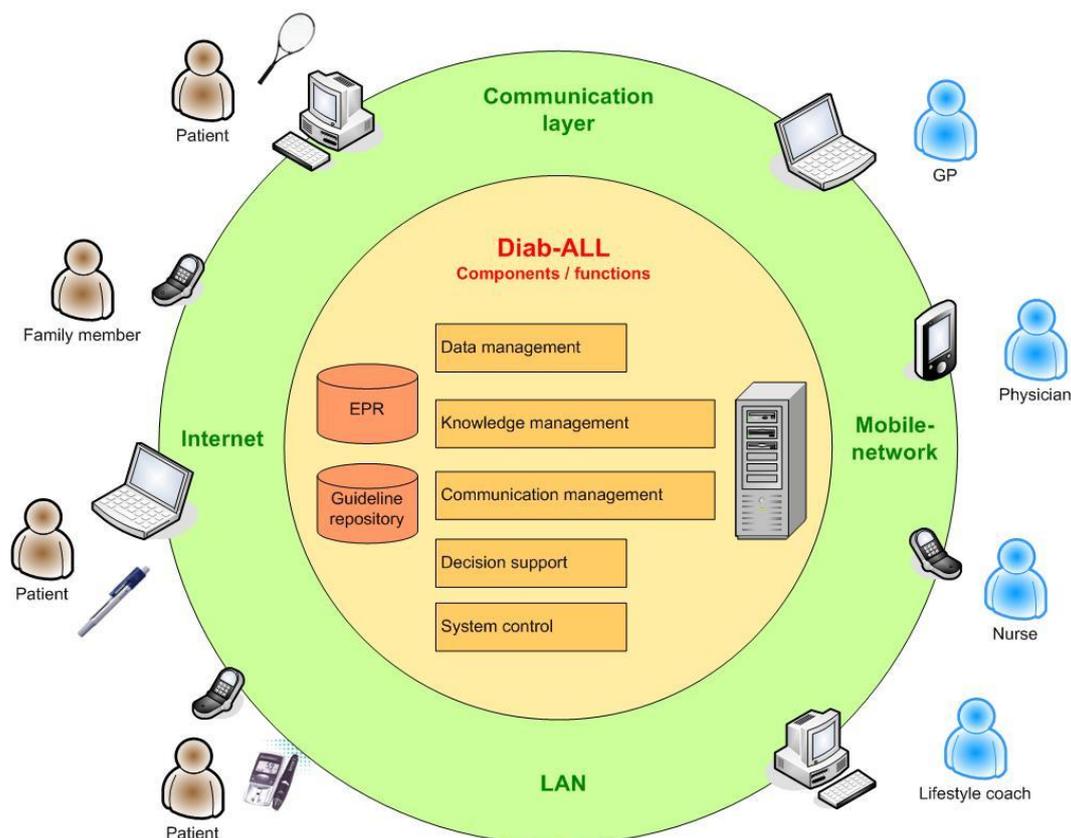


Figure 17: Functional architecture of a diabetes support system based on the MORE middleware

10.5 Summary

The advance of technology provides many possibilities to support the care of diabetic patients. A lot of research and commercial applications exist in the field. However, most of the existing applications are specialized to a well-defined functionality, and complex solutions

which support the entire care process can hardly be found. The various services are also not equally developed, and there are significant gaps where at most research applications exist. Monitoring support is the most common application field so far: there are various monitoring devices and electronic logbook software which allow the collection of data, but most of them require manual data entry. Many of these enable health professionals to access the collected data. Though as Klonoff et al. (2009) conclude, telemonitoring alone does not increase the effectiveness of the care. The evaluation of simple and ever-growing data sets and graphs provided by current applications needs time and expertise. The collected data needs to be automatically interpreted (i.e. turned into information) and preferably recommendations should be concluded in order to provide effective support. This kind of decision support is a promising field which is still mainly in research phase. Patient would need even more support as they need to perform self-management activities on a day-to-day basis without supervision from health professionals. ICT provides a great opportunity to facilitate the self-management activities of the patients. There are attempts to provide insulin dose calculations which are indeed useful, but most of the patients do not use insulin. They would rather need e.g. support and advices regarding their diet and physical activity. Moreover, all patients need an on-going, preferably personalized education and skills development. A plenty of resources can be found on internet, but these are usually general educational materials. In addition, patients cannot easily select the resources most appropriate to their actual knowledge, skills and problems.

11 Conclusions and Future Work

The Technology Watch task is part of the WP2 “User Centric Requirements Engineering and Validation”. The aim of this work package is to maintain a continuous discovery and analysis of user centric requirements, needs and prospects, to be used in the design, development, implementation and validation of the REACTION platform and services.

This document has surveyed developments in *Internet of Things* and *M2M* (Machine-to-Machine). These are two strong movements both in the commercial as well as the research world and over time these two areas will merge. All major stake-holders such as device manufacturers, telecom operators, service providers, are preparing for a future where every “thing” and/or device is connected. The main conclusion here is that REACTION needs to consider that our monitoring technology provided to the patient will have to co-exist and function together with already existing network of devices in the home of patients. It is not likely we can establish our separate infrastructure in the home of patients but will have to build on already existing infrastructures.

Event Management and Rule Engine technology are highly relevant and interesting areas but they still two fairly academic research areas where mature commercial products can easily be bought and used. REACTION as project need follow the developments and pursue its own experiments and prototyping. For Rule Engine technology it is recommended that we evaluate Drools for the third iteration.

Medical device connectivity was in focus during iteration one of the REACTION project, and the developed REACTION Device Connectivity Kit supports many different protocols. The slow growth of the number of devices supporting the Continua standards shows our approach to be all-inclusive and support not only Continua but ANT+ and other proprietary protocols many different device types remains still remains valid from an exploitation point of view.

The exploding apps market of course needs to be monitored. As have been explained there are numerous of patient apps available. However, we need to look for more substantial studies that can give evidence that these apps are actually useful for the patient in manage their diseases.

The overall conclusion from this technology watch is that REACTION is still well positioned with respect to on-going technology developments but more emphasis should be put on the patient side and technologies that help them self-manage their diseases.

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